Rapidlab™ 800

Operator's Manual

Bayer

115701 Rev C., 4/2000

The Rapidlab 800 system is for In Vitro Diagnostics Use.

The information in this manual was correct at the time of printing. However, Bayer Diagnostics continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

Contents

Figures

Using this Manual

Page

Using the 800 Series System Document Set

This manual is to be used with the Bayer Diagnostics 840, 844, 845, 850, 854, 855, 860, 864, and 865 systems. The manual provides the information and procedures necessary to operate and maintain any of the 800 series systems.

The Bayer Diagnostics 800 system document set includes the following:

- *Rapidlab 800 Operator's Manual*
- *Rapidlab 800 Quick Reference Guide*
- *Rapidlab 800 Interface Specification Manual*

These documents are designed to meet the needs of:

- medical technologists and laboratory technicians who use an 800 system on a daily basis, and who perform routine maintenance and troubleshooting
- respiratory therapists who use an 800 system to routinely analyze blood gas samples
- supervisors who customize their 800 system to meet their laboratory requirements

Refer to the table below to identify the appropriate document for the task you want to perform.

If you want to . . .	***Read . . .***
customize an 800 system to meet the requirements of your laboratory	*Rapidlab 800 Operator's Manual*
perform daily operating procedures	*Rapidlab 800 Operator's Manual*
review the 800 system components and principles of operation	*Rapidlab 800 Operator's Manual*
perform routine maintenance and troubleshooting	*Rapidlab 800 Operator's Manual*
review procedures for routine maintenance and troubleshooting	*Rapidlab 800 Quick Reference Guide*

Finding Information in this Manual

Use this section to identify the sections in this manual that describe the 800 system and the tasks associated with operating and maintaining the system.

If you need to . . .	*Then read . . .*
review system features and capabilities and the theory and principles of operation	Section 1, *Learning About the System*
identify 800 series system components, including the user interface	Section 1, *Learning About the System*
review sample requirements and reagent information	Section 1, *Learning About the System*
analyze samples, QC, and calibrators	Section 2, *Operating the System*
perform system maintenance	Section 3, *Maintaining the System*
identify the appropriate corrective action to resolve operating problems	Section 4, *Troubleshooting the System*
customize an 800 series system to meet your laboratory's requirements	Section 5, *System Administration*
back up and archive data files	Section 5, *System Administration*
install a new version of the software	Section 5, *System Administration*
shut down the system	Section 5, *System Administration*
review important information about biohazardous conditions	Appendix A, *Protecting Yourself from Biohazards*

(Continued)

If you need to . . .	*Then read . . .*
obtain service and technical information and order supplies	Appendix B, *Service and Supplies*
review a bibliography of references	Appendix C, *References*
interface external devices, such as a CO-oximeter or a laboratory information system	Appendix D, *Connecting to External Devices*
review system performance characteristics	Appendix E, *Performance Characteristics*
review patient sample reports	Appendix F, *Printed Reports*
install the system	Appendix H, *Installation*
review the analytic principles of the sensors and the calculations performed by the system	Appendix I, *Operating Principles*
review the technical bulletin about water quality	Appendix J, *Water Quality Technical Bulletin*
record scheduled maintenance procedures and workload statistics	Appendix K, *Maintenance Checklist Charts*
review key terms describing the 800 system and its operation	*Glossary*
change the slope and offset values to provide correlation with other analyzers	Appendix G, *Correlation Adjustment*

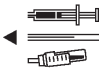
Conventions Used in this Manual

The Operator's Manual uses the following text and symbol conventions throughout the document.

Convention	Description
Bold	Bold type indicates a key option that appears on the keypad, or the screen. For example, if the word 'enter' appears as **Enter**, it refers to the **Enter** key you press to store a value or accept an option.
italic	Italic type refers to a document in the 800 series document set or to a section title within a document. For example, *Maintaining the System* refers to Section 3 of this manual.
WARNING	Warning statements provide information about a condition that may cause personal injury.
CAUTION:	Caution statements provide information about a condition that may cause product damage or loss of data.
BIOHAZARD:	Biohazard statements alert you to potentially biohazardous conditions.
NOTE:	The note symbol is used with important information that requires your attention.
840	This symbol indicates that the information or procedure applies to an 840, 844, and an 845 systems.
850	This symbol indicates that the information or procedure applies to an 850, 854, and an 855 systems.
860	This symbol indicates that the information or procedure applies to an 860, 864, and an 865 systems.
CO-ox	This is the abbreviation used for systems with a CO-oximeter module attached.
Procedural Notes	Procedural notes appear after many of the procedures in the *Rapidlab 800 Operator's Manual.* They explain conditions that can happen when a procedure is not performed as intended. They also contain brief explanations about how to handle an unexpected situation or how to discontinue a process.

Understanding the Symbols

This section describes the symbols that may appear on the exterior of the system. The symbols provide you with the location of certain components and with warnings for proper operation.

Symbol	Description
	This symbol warns you of a possible burn hazard for the lamp. Wait at least 5 minutes after the lamp has been off to allow sufficient time for it to cool.
	This symbol indicates where you insert the sample device (syringe, capillary, or ampule) to perform analysis.
	This symbol cautions you about the risk of exposure to biohazards.
	This symbol cautions you about the risk of exposure to potential electrical hazards.
	This symbol indicates that the input electricity is alternating current.
	This symbol alerts you to important information about the fuses.
	This symbol identifies that the system is type B equipment, which provides a particular degree of protection against electric shock.
Class 1	This symbol indicates that the system is class 1 type equipment, which has basic insulation and additional safety grounding precautions.
	This symbol indicates that the system is approved by UL as meeting U.S. requirements for safety.
	This symbol indicates that the system meets the requirements of the European Union.
	This symbol indicates that the system is approved by CSA as meeting the U.S. and Canadian requirements for safety.

1 Learning About the System

Page

Intended Use

The *Rapidlab 800 Operator's Manual* accompanies the 800 series systems—base models 840, 850, 860—and base models with the oximetry module—models 844, 854, 864— and base models with the CO-ox module—models 845, 855, 865. These systems are used for the determination of pO_2, pCO_2, pH, sodium (Na^+), potassium (K^+), ionized calcium (Ca^{++}), chloride (Cl^-), glucose, lactate, tHb, and hemoglobin derivatives in arterial, venous, and capillary whole blood samples.

System	Parameters Determined and Reported
840	pO_2, pCO_2, pH
850	pO_2, pCO_2, pH, Na^+, K^+, Ca^{++}, Cl^-
860	pO_2, pCO_2, glucose, lactate, pH, Na^+, K^+, Ca^{++}, Cl^-
844	pO_2, pCO_2, pH, tHb, FO_2Hb
854	pO_2, pCO_2, pH, Na^+, K^+, Ca^{++}, Cl^-, tHb, FO_2Hb
864	pO_2, pCO_2, glucose, lactate, pH, Na^+, K^+, Ca^{++}, Cl^-, tHb, FO_2Hb
845	pO_2, pCO_2, pH, tHb, FO_2Hb, *F*HHb, *F*MetHb, *F*COHb
855	pO_2, pCO_2, pH, Na^+, K^+, Ca^{++}, Cl^-, tHb, FO_2Hb, *F*HHb, *F*MetHb, *F*COHb
865	pO_2, pCO_2, glucose, lactate, pH, Na^+, K^+, Ca^{++}, Cl^-, tHb, FO_2Hb, *F*HHb, *F*MetHb, *F*COHb

The 800 systems also report results for the following parameters:

- actual and standard bicarbonate (HCO_3^-)
- total carbon dioxide ($ctCO_2$)
- base excess of blood [BE(B)] and of extracellular fluid [BE(ecf)]
- estimated oxygen saturation (O_2SAT) – for 840, 850 and 860 models
- estimated oxygen content (O_2CT) – for 840, 850 and 860 models
- temperature corrected pH [pH(T)]
- temperature corrected pCO_2 [pCO_2(T)]
- temperature corrected pO_2 [pO_2(T)]
- temperature corrected alveolar-arterial oxygen tension difference [pO_2(A–a)(T)]
- temperature corrected arterial-alveolar oxygen tension ratio [pO_2(a/A)(T)]
- temperature corrected respiratory index [RI(T)]

850 860

The 850 and 860 systems report the following parameters:

- calcium ion concentration adjusted to pH 7.4 [Ca^{++} (7.4)]
- anion gap (AnGap)

In addition, the 844, 845, 854, 855, 864, and 865 systems report the following parameters:

- hematocrit
- hemoglobin oxygen saturation (sO_2)
- oxygen content of hemoglobin [ctO_2(Hb)]
- oxygen capacity of hemoglobin (O_2CAP)
- partial pressure of oxygen at 50% saturation (p50)
- sulfhemoglobin concentrations greater than 1.5%
- arterial oxygen content [ctO_2(a)]
- venous oxygen content [ctO_2(v)]
- estimated shunt [Qsp/Qt(est,T)]

The 844, 845, 854, 855, 864, and 865 systems report the following parameters for a-v studies:

- arterial venous oxygen content difference [ctO_2(a-v)]
- a-v extraction index [ctO_2([a-v]/a)]
- oxygen consumption rate (VO_2)
- oxygen delivery (DO_2)
- physiologic shunt [Qsp/Qt(T)]

Features

The 800 system offers advanced features for analyzing samples, managing patient results and QC data, and customizing the system. These features are designed to enhance operator safety, to enhance ease of use, to enhance reliability, and to reduce maintenance.

Task	Features
analyzing samples	fully automated sampler that controls sample delivery with a technique-independent sample entry
	automated sample entry that minimizes exposure to the sample probe and to biohazardous sample aerosols and spills
	easy analysis of sample types and devices with small sample size
	illuminated sample path in the base model measurement module for visibility during analysis
	easy-to-use, menu-driven software and on-screen prompts
	online assistance using an integrated Help program
	optional bar coding capabilities for patient ID and accession numbers
managing patient results and QC data	flags for results that fall outside expected ranges
	optional laser bar code scanner to streamline data entry
	QC analysis with range checking, statistical summary reports, and Levey-Jennings charts for up to 12 control materials
	all measured parameters for one month's QC data displayed on the screen
	capacity to store up to 5000 patient sample reports
	onboard roll printer with paper take-up spool
	variety of patient report formats on roll printer and optional line printer
customizing the user-definable features	system software that you can customize to meet your laboratory requirements
	automatic calibration at intervals that you select
	QC ranges, patient reference ranges, patient sample storage and printing options that you can customize

(Continued)

Task	Features
maintenance and troubleshooting	low maintenance Ready® Sensors reduced number of system parts and system complexity waste system designed for biosafety automatic, reagent-path cleaning cycle
expanding system capabilities	advanced on-board data management bidirectional communication with your information systems and Chiron Diagnostics data management systems combined results with an optional CO-ox full-page reports (8.5 x 11 inches) with an optional line printer archive and backup capabilities

Description of the System

The following series of illustrations show the exterior controls and components of the 800 system. The 860, 864, and 865 systems have five reagent bottles, and the 840, 844, 845, 850, 854, and 855 systems have four reagent bottles.

Figure 1-1. Front View (with cover) of an 860

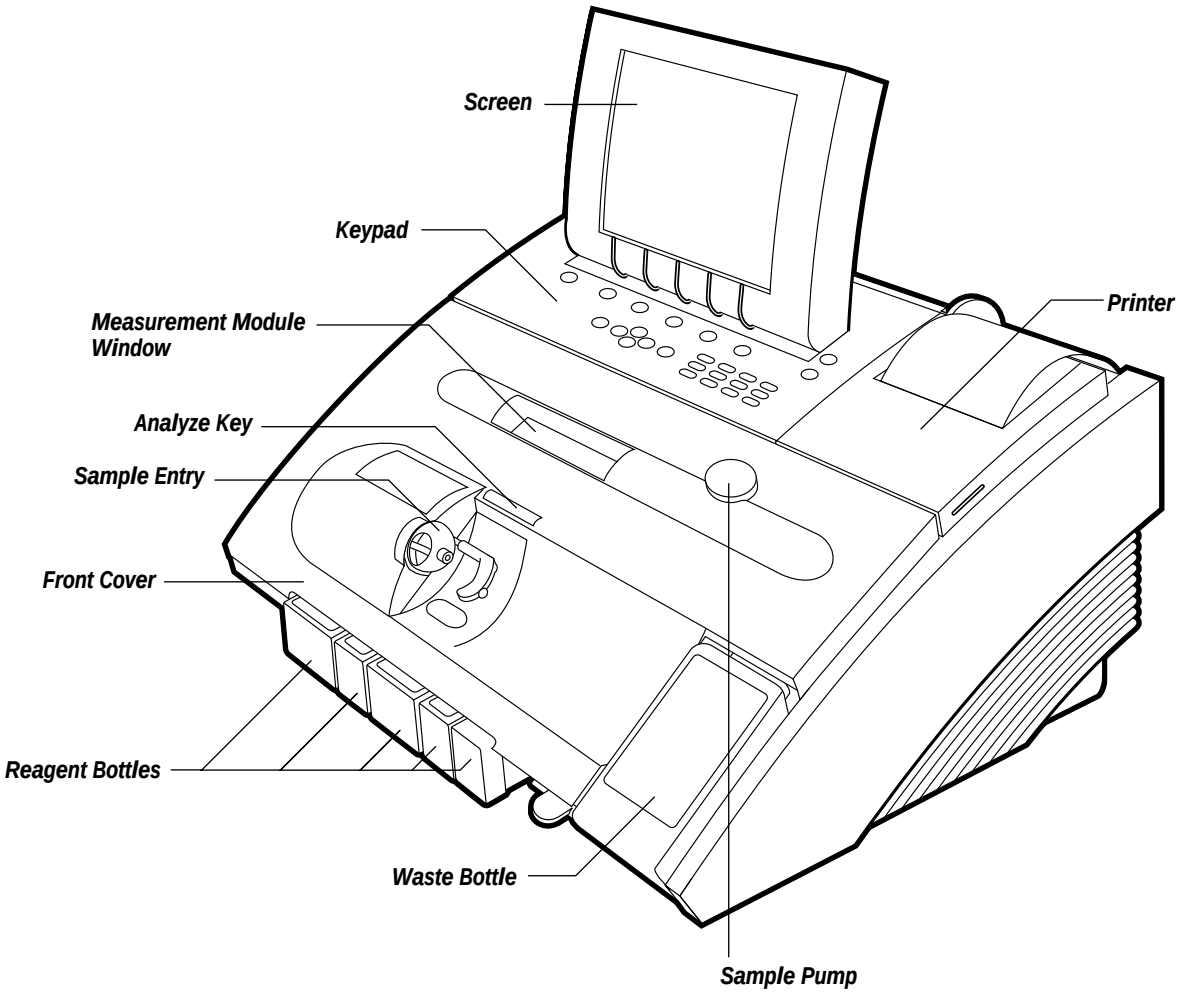


Figure 1-2. Front View (without cover) of an 860

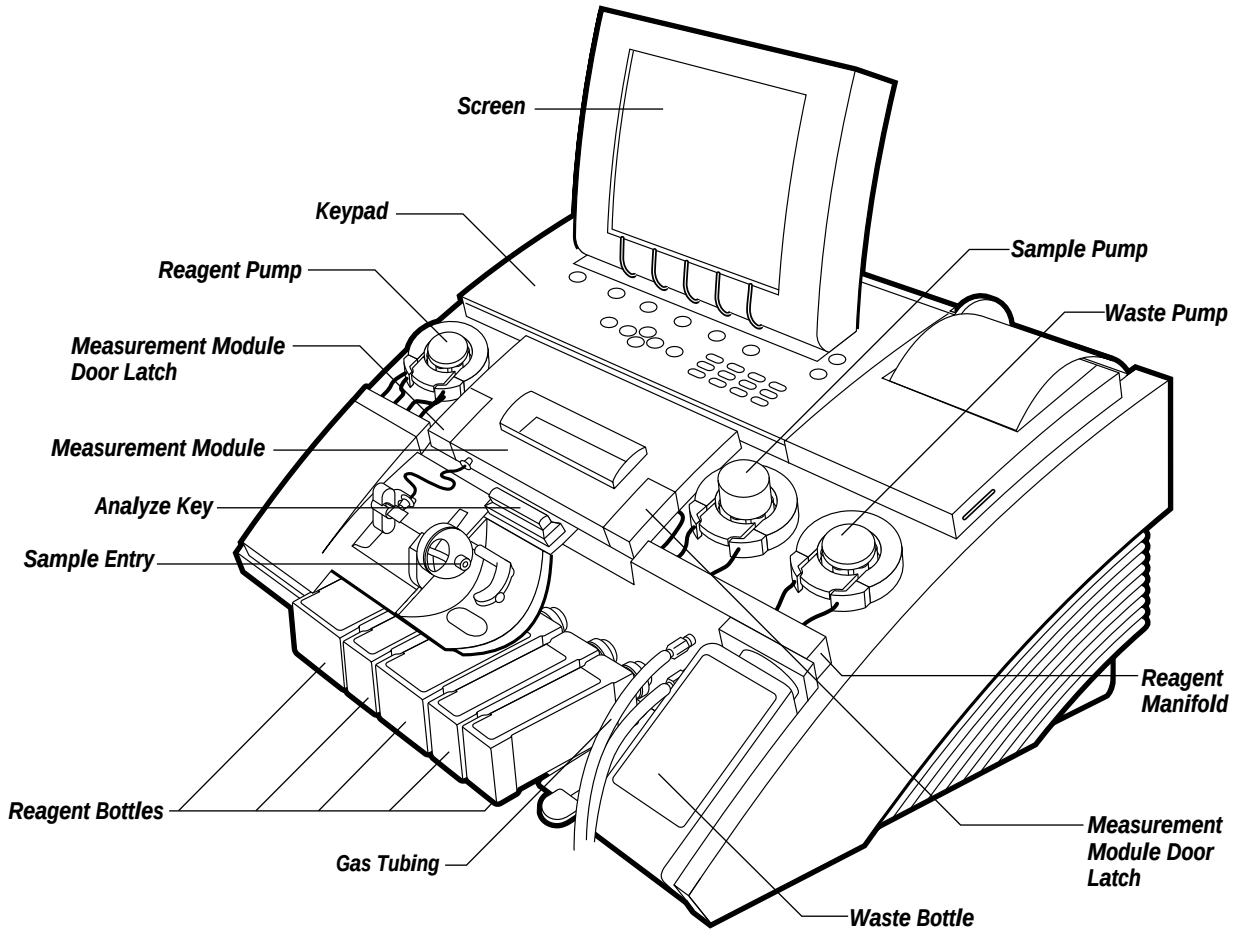


Figure 1-3. Front View (without cover) of an 865

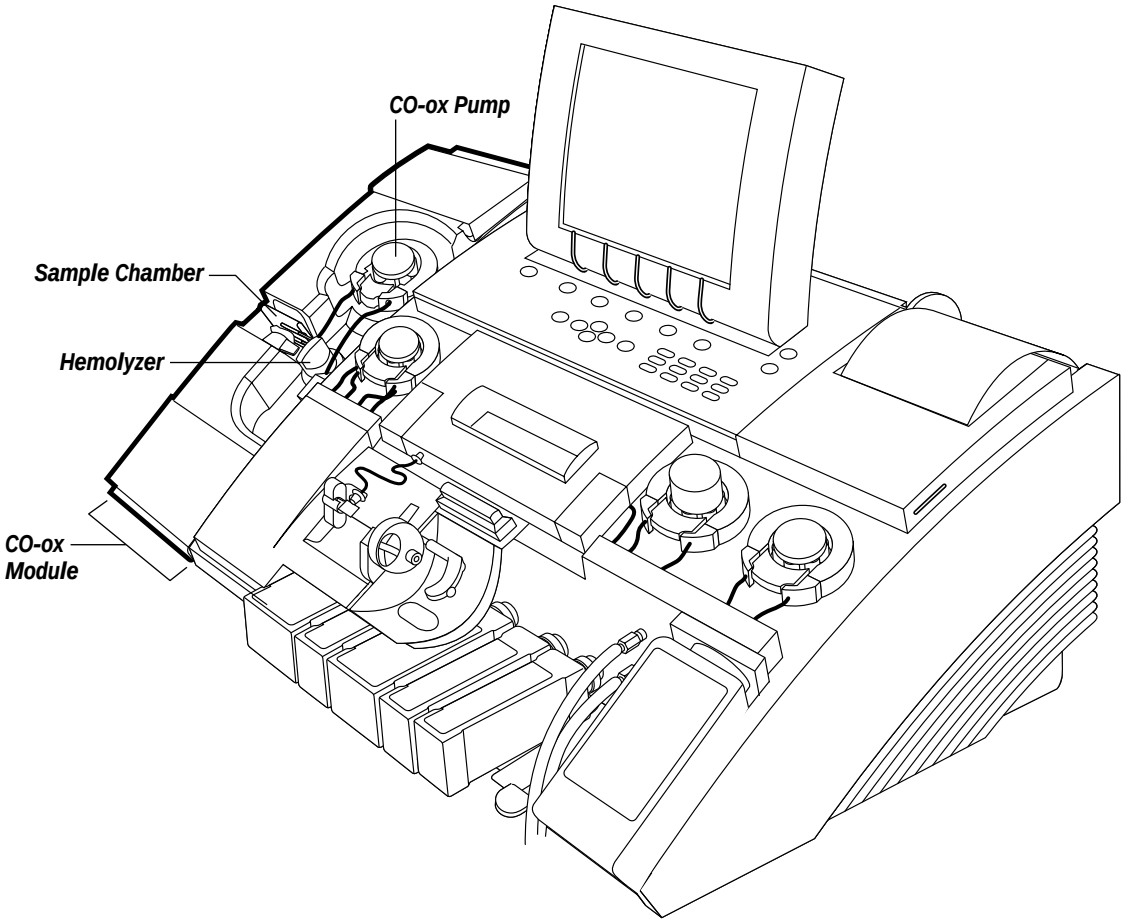


Figure 1-4. Side View

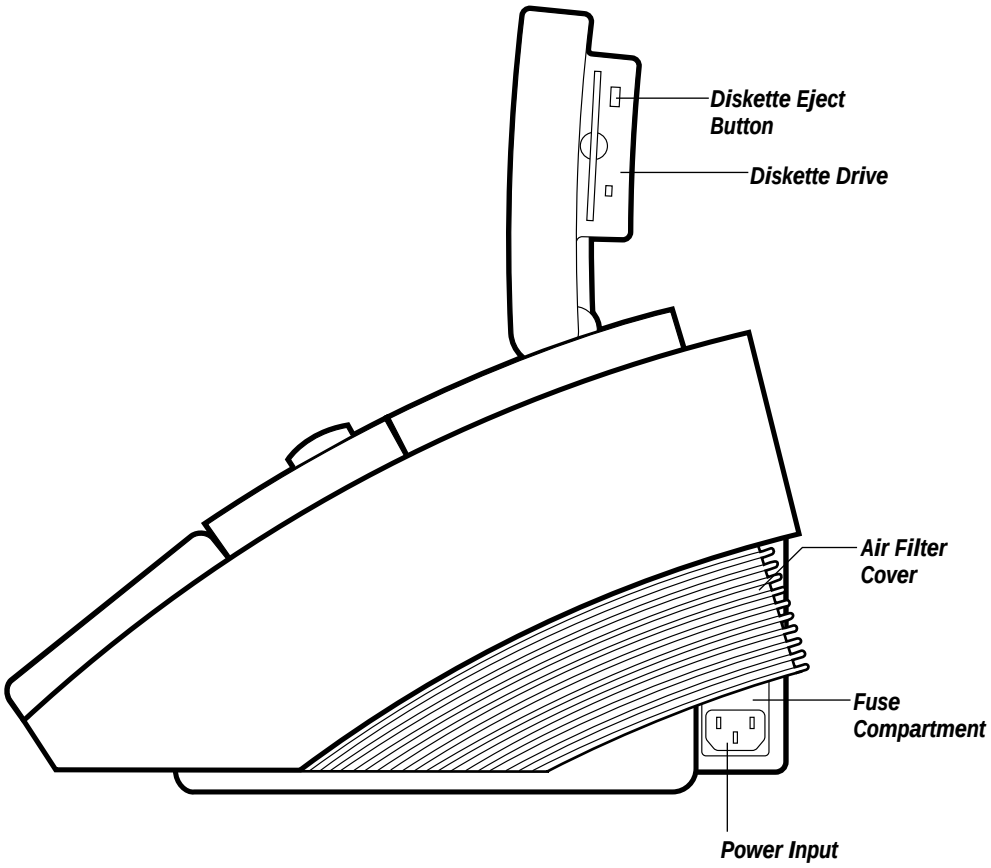


Figure 1-5. Rear View with CO-ox Module

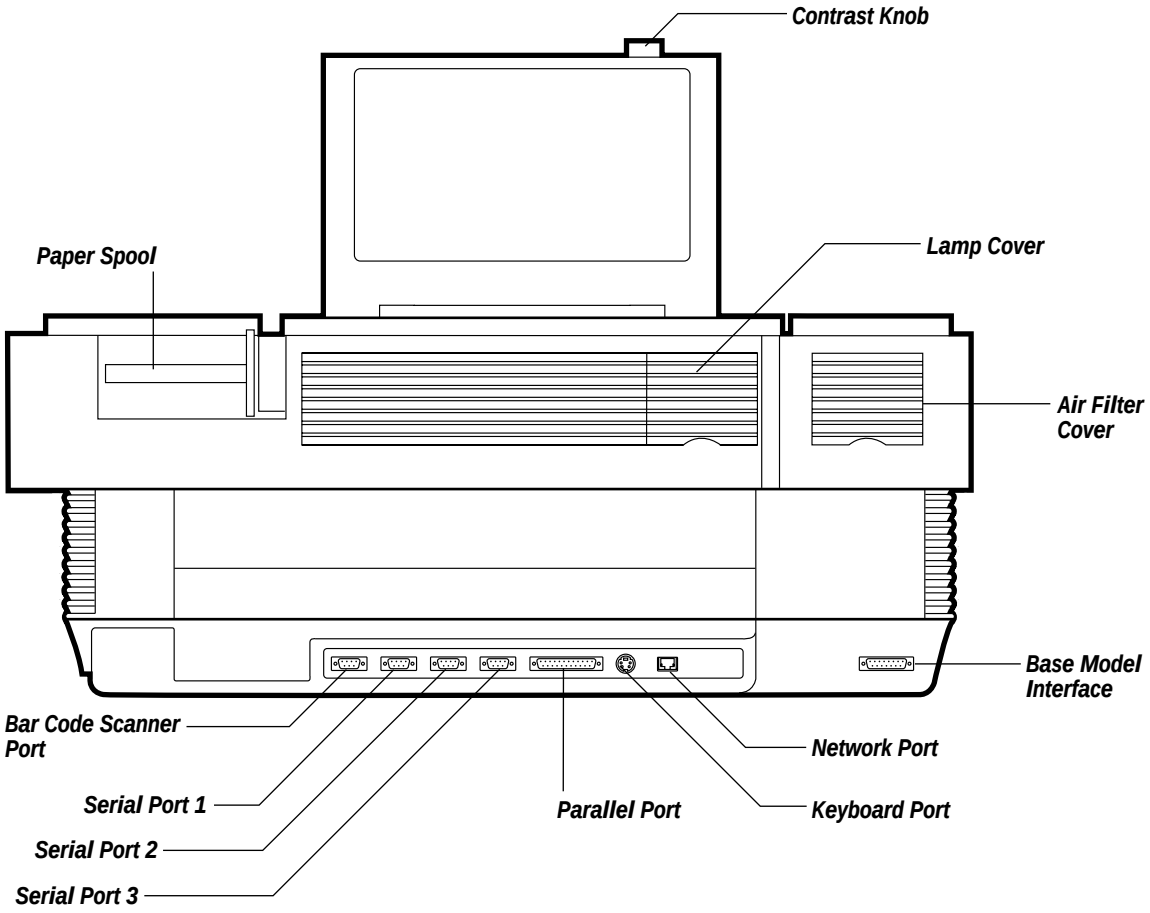
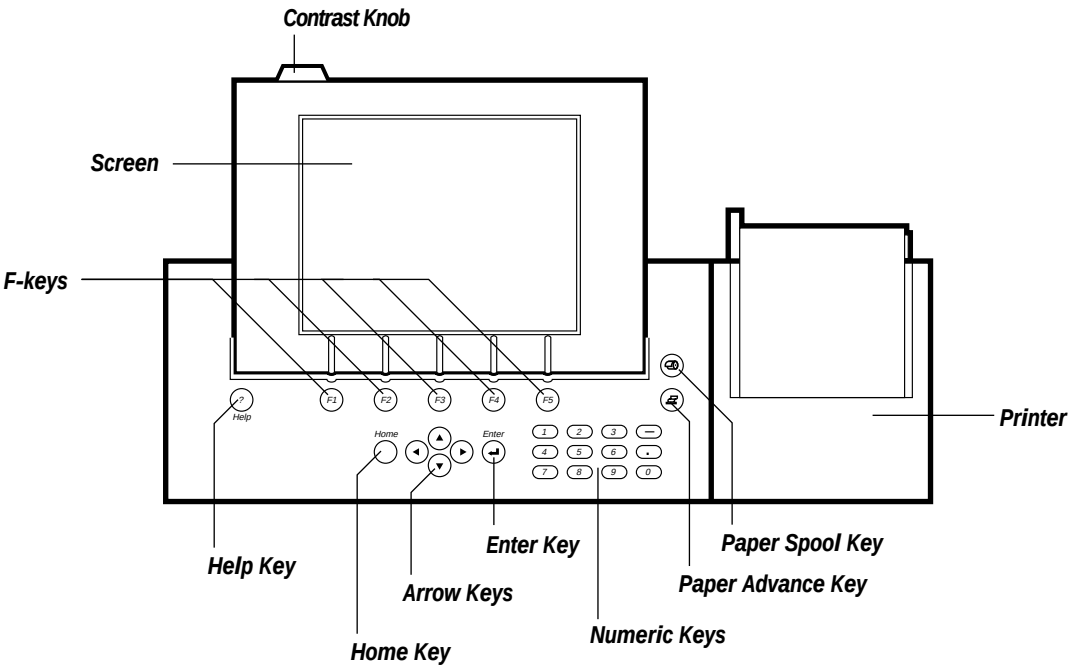


Figure 1-6. Screen and Keys



System Components

The 800 system components consist of the following functional groups:

- base model measurement module
- CO-ox model measurement module
- fluidic components
- electronic components

Measurement Module Components

The following illustrations show the measurement module components. Table 1-1 describes these components and their functions.

Table 1-1. Measurement Module Components

Component	Description
Preheater	The preheater warms the sample to 37°C.
Sensors	The sensors detect analytes present in the sample and form the actual sample path. The sample leaves the sample path through the measurement module tubing after analysis. Refer to Appendix I, *Operating Principles*, for more information about each sensor.
Sample Ground/ Temperature Sensor	The sample ground/temperature sensor provides an electrical grounding mechanism for stable sensor readings and also measures the sample temperature.
Measurement Block	The temperature-controlled measurement block contains the sensors and ensures a constant temperature of 37°C during analysis.
Spring-loaded Latch	The spring-loaded latch keeps the sensors aligned in the measurement block. The latch locks open for easy removal of the sensors. The release tab on the latch releases the latch to close it.
Contact Assembly	The contact assembly provides electrical contacts between the sensors and the system.

Figure 1-7. 840 Measurement Module Components

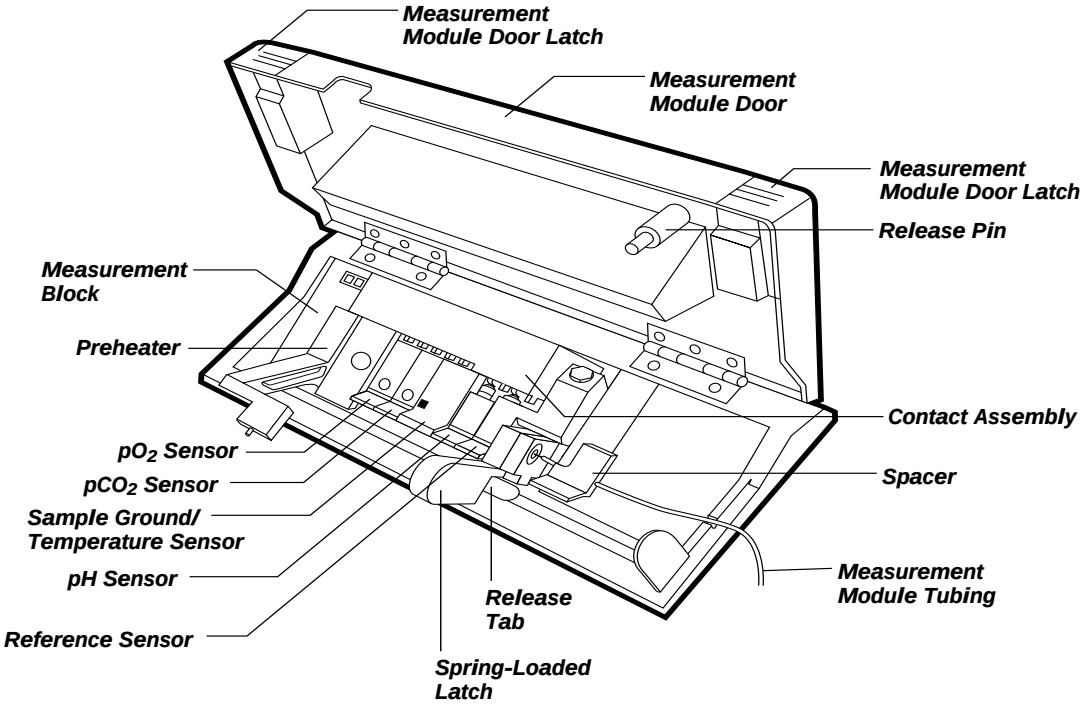


Figure 1-8. 850 Measurement Module Components

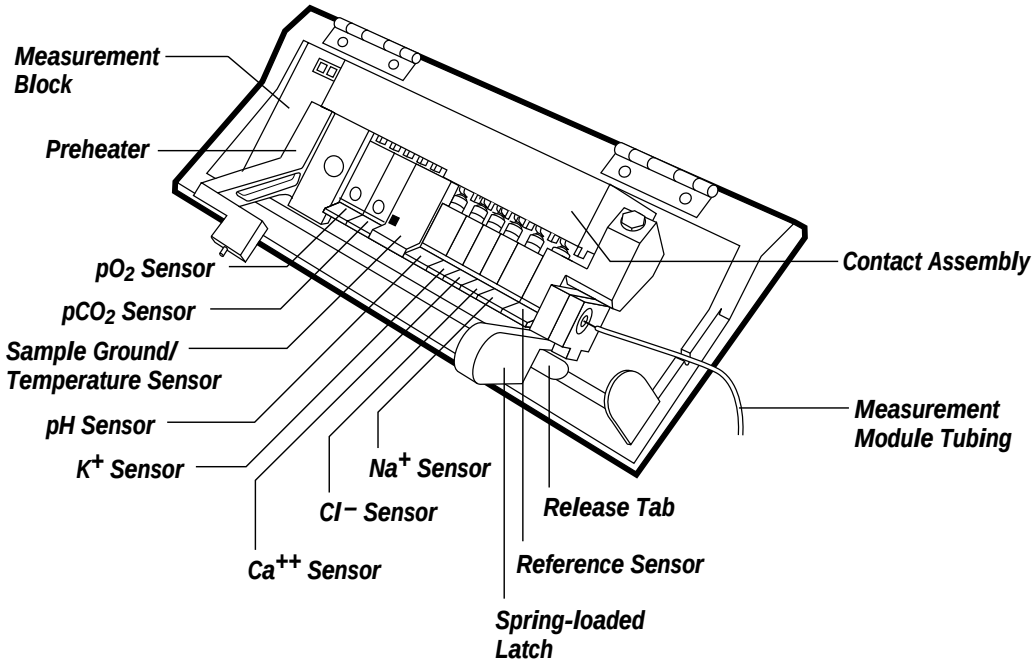
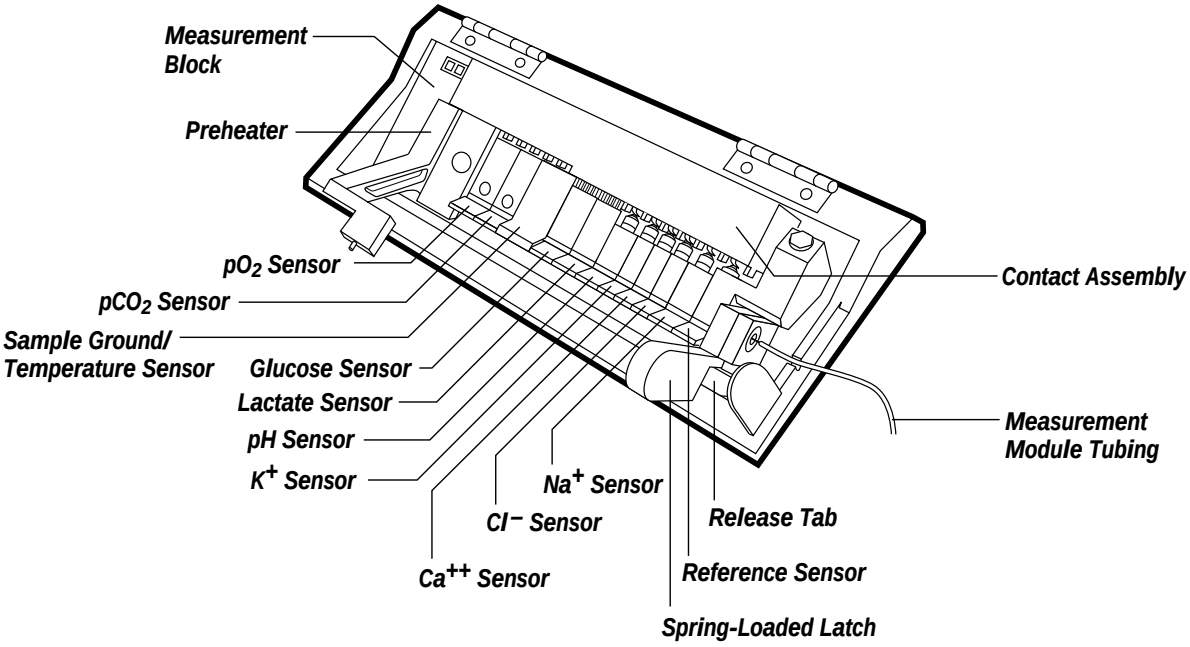


Figure 1-9. 860 Measurement Module Components



CO-ox Module Measurement Components

The CO-ox module is connected to the base model, which supplies power to the module. The 844, 854, and 864 systems analyze samples for tHb and FO_2Hb; the 845, 855, and 865 systems anlayze samples for tHb, FO_2Hb, *F*HHb, *F*MetHb, and *F*COHb. The measurement components spectrophotometrically measure tHb and its derivatives. Most of the measurement components are enclosed in the CO-ox module. The sample chamber is visible when the CO-ox cover is raised.

Optics Module and Lamp

The lamp provides the light to illuminate the sample. The optics module includes lenses and filters, fiber optic coupler, and polychromator. The lenses and filters focus the light from the lamp to the fiber optic coupler. The fiber optic coupler transports the light to the sample chamber. The polychromator, which consists of coupling lenses, entrance slit, mirrors, and diode array, disperses the light that passes through the sample chamber into a spectrum and measures the light intensity at several wavelengths.

Sample Chamber

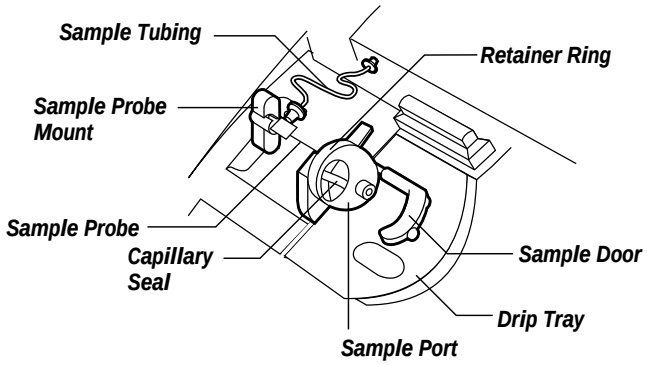
The hemoglobin content is measured in the sample chamber, which is located between the fiber optics and the polychromator. After passing through the hemolyzer, the sample moves to the sample chamber where it is warmed to 37°C.

Fluidic Components

The fluidic components move fluids, gases, and samples through the 800 system. The electronic components direct the fluidic components in response to the user interface and automatic system activities. The CO-ox module uses the fluidic components of the base model and additional components.

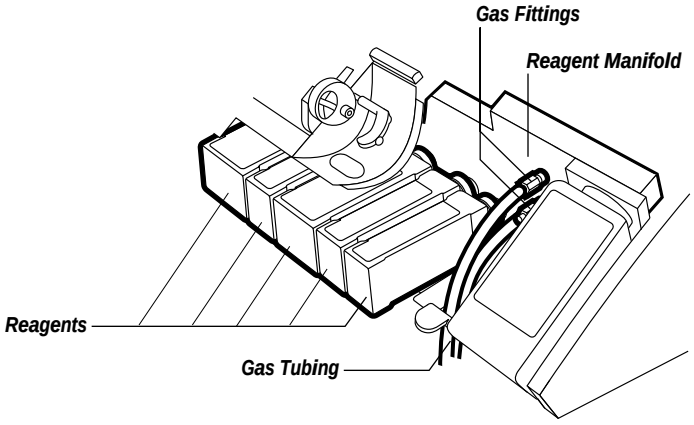
Sample Entry

The sample entry components, shown in the illustration below, include the sample port and its components, the sample door, the sample probe, and the sample tubing. You introduce samples into the system through these components.



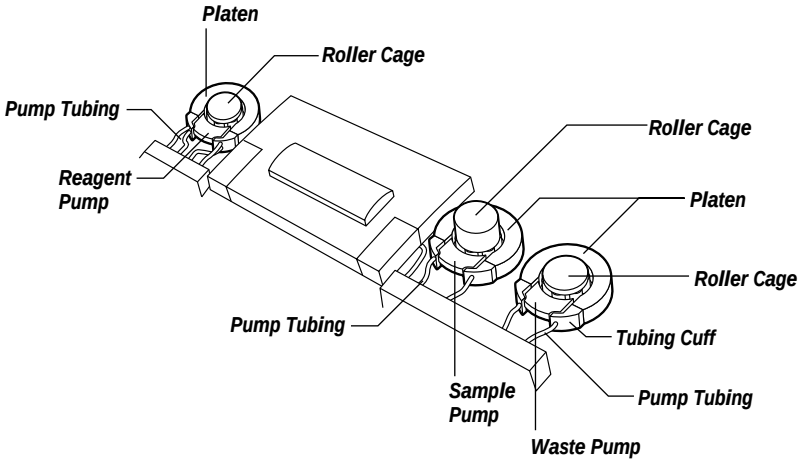
Reagent Delivery

The reagent delivery components include the reagents, the gases, and the solenoid valves that direct the movement of reagents, ambient air, and gases through the system. The opening and closing of the 11 solenoid valves allow the fluids and gases to pass through the system. The solenoid valves are located in the reagent manifold. The illustration below shows the reagent delivery components for 860, 864, and 865 systems.



Pumps

The system pumps are the reagent pump, the sample pump, the waste pump, and the CO-ox pump if the CO-ox module is attached. Each pump consists of a platen, tubing, a roller cage, and a motor located behind the pump. The tubing is located between the platens and the rollers on the roller cage. The pressure applied by the roller cage against the platen creates a peristaltic action to move the fluid in the tubing.

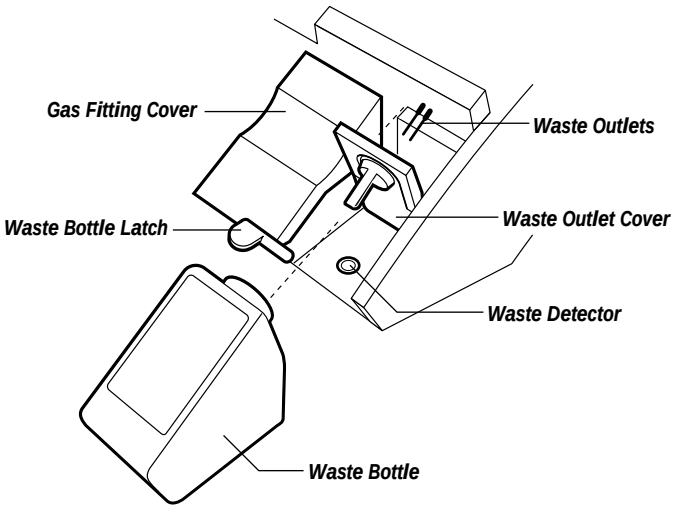


Fluid Detectors

The five fluid detectors in the base model sense the presence, type, and continuity of fluids in the system. Fluid detectors 1, 1A, and 2 are associated with the measurement block. These detectors ensure that the sample is positioned correctly for accurate measurement. Detectors 3 and 4, located in the reagent manifold, sense the presence of the reagents in the system. The CO-ox module adds fluid detector 5 to the system. This detector and the CO-ox sample chamber sense the presence of a sample in the CO-ox module.

Waste

The waste components include the waste bottle and latch, the waste outlets, the waste outlet cover, and the waste detector. The waste components accept waste reagents and sample pumped from the fluidic components. The waste detector detects the presence of the waste bottle and also detects when the bottle is full.



Sample Connector

The sample connector, located in the measurement module of the base model, connects the sample tubing in the base model with the sample tubing in the CO-ox module.

Hemolyzer

The hemolyzer uses ultrasonic sound vibrations to rupture red blood cell membranes and release hemoglobin molecules. These vibrations also rupture other cells in the sample, reducing the light scattering from whole cells that can interfere with hemoglobin analysis in the sample chamber. All CO-ox module samples pass through the hemolyzer before entering the sample chamber.

Electronic Components

The electronic components direct the operation of all system components. The electronic components communicate with fluidic, measurement, and CO-ox module components, and with external devices. The electronic components obtain information from the sensors and perform all calculations required to determine reported parameters. Table 1-2 describes these components and their functions.

Table 1-2. Electronic Components

component	*Description*
Power Supply	Converts the line voltage from AC to DC and then provides power to the rest of the system
Real Time Processor (RTP)	Sends commands to other PC boards to perform system activities; the RTP controls the fluidic system, acquires data from the measurement module, calculates parameters, and communicates with the user-interface processor
User-Interface Processor (UIP)	Controls user interaction with the screen, the bar code scanner, the printer, the database, and the external communication ports
Backplane	Distributes power to each of the attached PC boards; the backplane connectors route signals to electronic and electromechanical subsystems
Control Board	Contains all of the drivers to control the fluidic system valves and pumps, the preheater, and the sample port
Data Acquisition System Board (DAS)	Performs the analog to digital conversion for a selected measurement channel; after the conversion, the data is sent to the RTP PC board for any required calculations
Printer Control	Receives information from the UIP and directs the roll printer to print reports

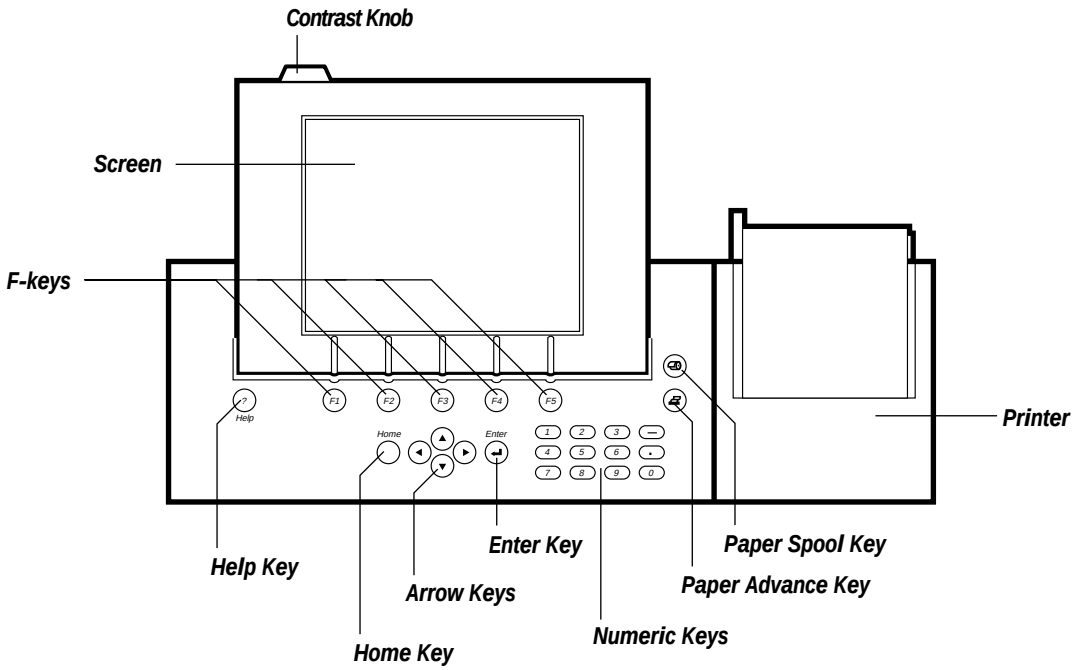
(Continued)

component	*Description*
Preamplifier (Preamp)	Amplifies the signal from each sensor and sends those signals to the premux PC board for selection
Premultiplexer (Premux)	Selects the channel to be read and provides programmable gain; the premux board then sends the signal to the DAS PC board.
CO-ox Array Board (CAB)	Produces current proportional to the amount of energy generated by the optics and provides a coarse alignment of the diode array with the polychromator
CO-ox Measurement Board (CMB)	Provides control signals to and collects and limits the signals from the array board; this board also detects fluid in the sample chamber and supplies reference values for the measurement
CO-ox Processor Board (CPB)	Interfaces to the power supply and the drivers to control the pump and heater in the CO-ox module; this board communicates with other boards in the CO-ox module and base model

User Interface

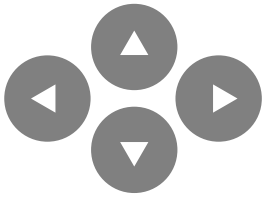
The user interface, shown in Figure 1-10, consists of components that you use to direct system activities and obtain operating status information.

Figure 1-10. Screen and Keys



System Keys

You use the system keys to direct system activities and to move through the software. The 800 system has the following keys:

Key	Description	Action
Analyze		starts analysis
arrows		move the cursor in the direction of the selected arrow
Enter	Enter 	accepts selected options and moves from field to field; on the Ready screen it displays the Reagent Levels screen
Help	 Help	accesses the Help screen
Home	Home 	accesses the Ready screen; use this key to return to the Ready screen from any other screen
numeric		types data into text fields
paper advance		advances the paper on the roll printer

(Continued)

Key	Description	Action
paper spool		winds the paper on the paper spool
F-keys		accesses the function that appears in the F-key labels on the screen above each key; the labels can vary with each screen

Optional Keyboard

You can use an IBM® AT® compatible, 101-key, alpha-numeric keyboard to operate an 800 system. Use the following keys on the keyboard to simulate the system keys on the 800 system keypad:

800 System Keypad	Keyboard
Analyze	F8
Roll Printer Paper Advance	F7
Help	F9
Home	Home
Enter	Enter
F1, F2, F3, F4, F5	F1, F2, F3, F4, F5
Arrow keys	Arrow keys

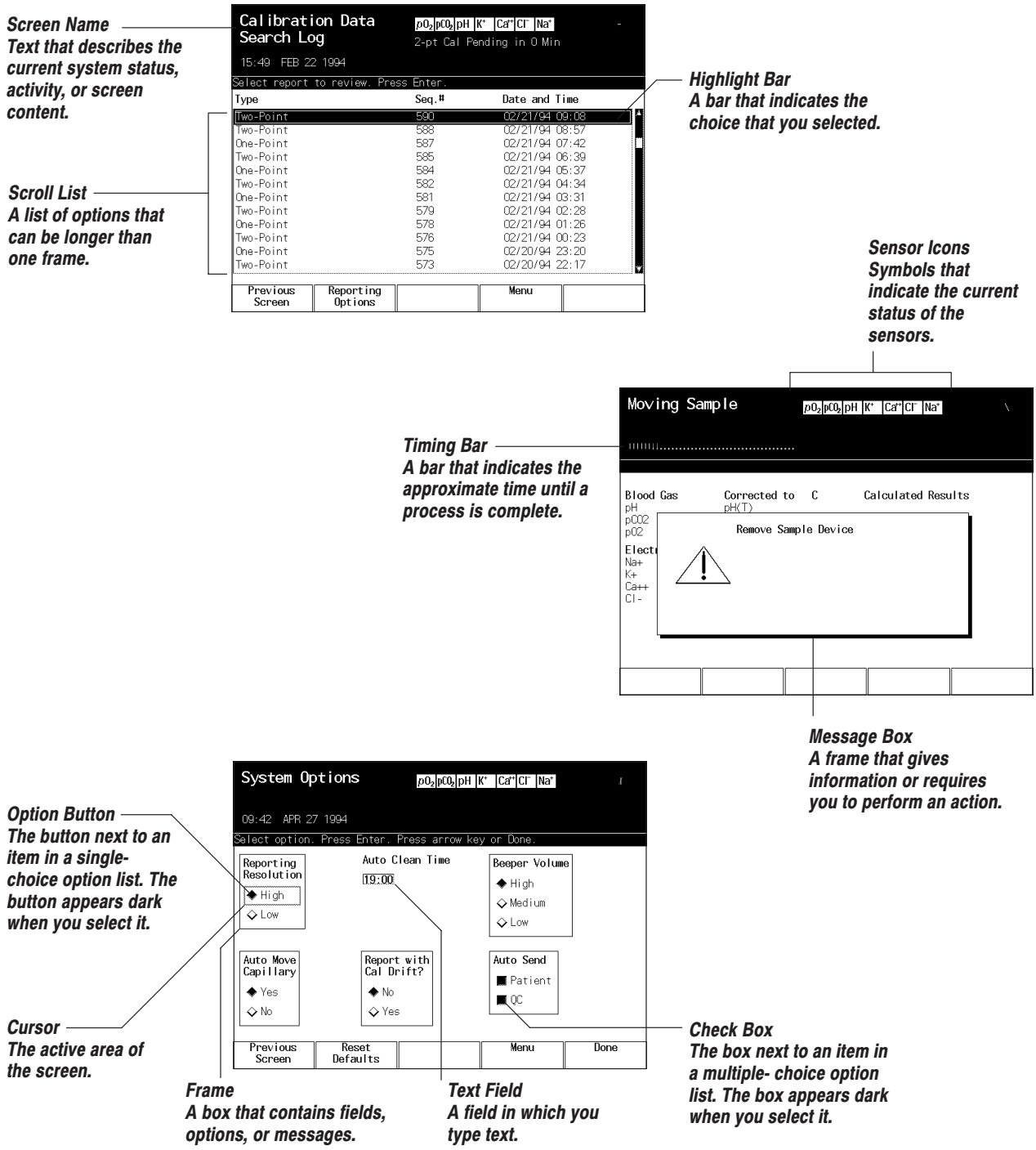
F-keys

You use F-keys to access functions that appear on the screen above each key. The F-key labels can vary with each screen. The following keys are some of the more commonly used F-keys.

Press . . .	***To . . .***
Previous Screen	return to the frame or screen from which you accessed the current screen.
More Results	display a screen that contains additional results. This key appears only when another results screen is available.
Send	transmit sample results to a connected LIS, HIS, or data management system. This key appears on the Results screen only if Auto Send is off.
Do Not Send	prevent the transmission of sample results to a connected LIS, HIS, or data management system. This key appears on the Results screen only if Auto Send is off.
Cancel	stop a current sample analysis or calibration. Cancel also appears in some message boxes and lets you close the message box without taking any action.
Change Parameters	select panels to use for sample analysis.
Change Sample Type	select a type of sample to use for sample analysis.
Calibrate	select a calibration to initiate.

Screen Elements

Screen elements are the components on the screen that enable you to interact with the system software.

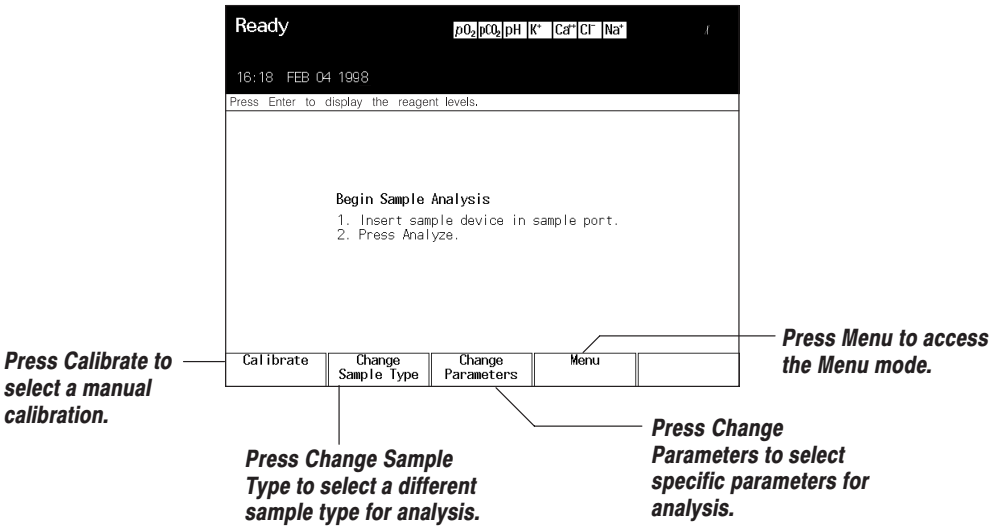


Sensor icons appear in the status area of the screen. Each sensor is represented by a box containing the sensor label. The CO-ox module is represented by the tHb icon in the sensor bar. The sensor icons indicate the current status of each sensor installed on the system.

If the sensor icon is . . .	*Then the sensor is . . .*
a green box with black text	turned on and in calibration.
a yellow box with black text and a slash across the label	turned on but out of calibration.
not visible	turned off or not installed.

Using the Analyze Mode

The Analyze mode is the operating mode where you perform the most frequently required functions. When the system is ready to analyze samples, the Ready screen appears with the Begin Sample Analysis message box. The F-key labels shown below appear at the bottom of the Ready screen.

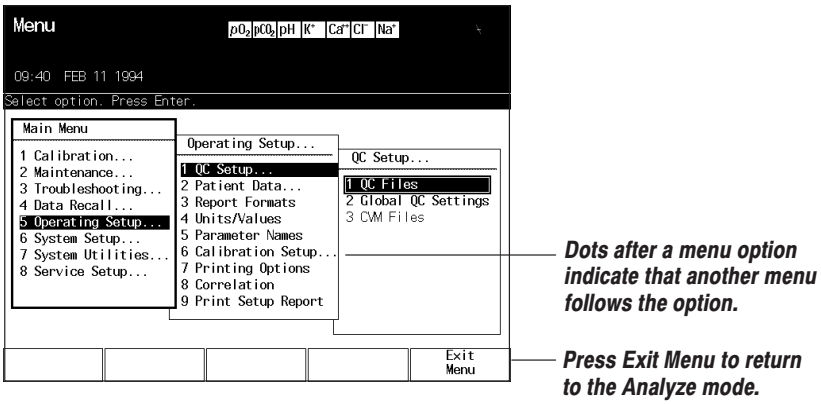


Using the Menu Mode

The Menu mode lets you perform infrequently required functions. You access the Menu mode by pressing Menu. The system displays the Menu screen with the first option in the Main Menu highlighted.

Use the arrow keys to move up and down a menu to highlight the option you want. As you highlight an option in the Main Menu, another menu appears to the right. This menu lets you preview the options available on the next menu. The preview menu helps you locate the next menu option
you want.

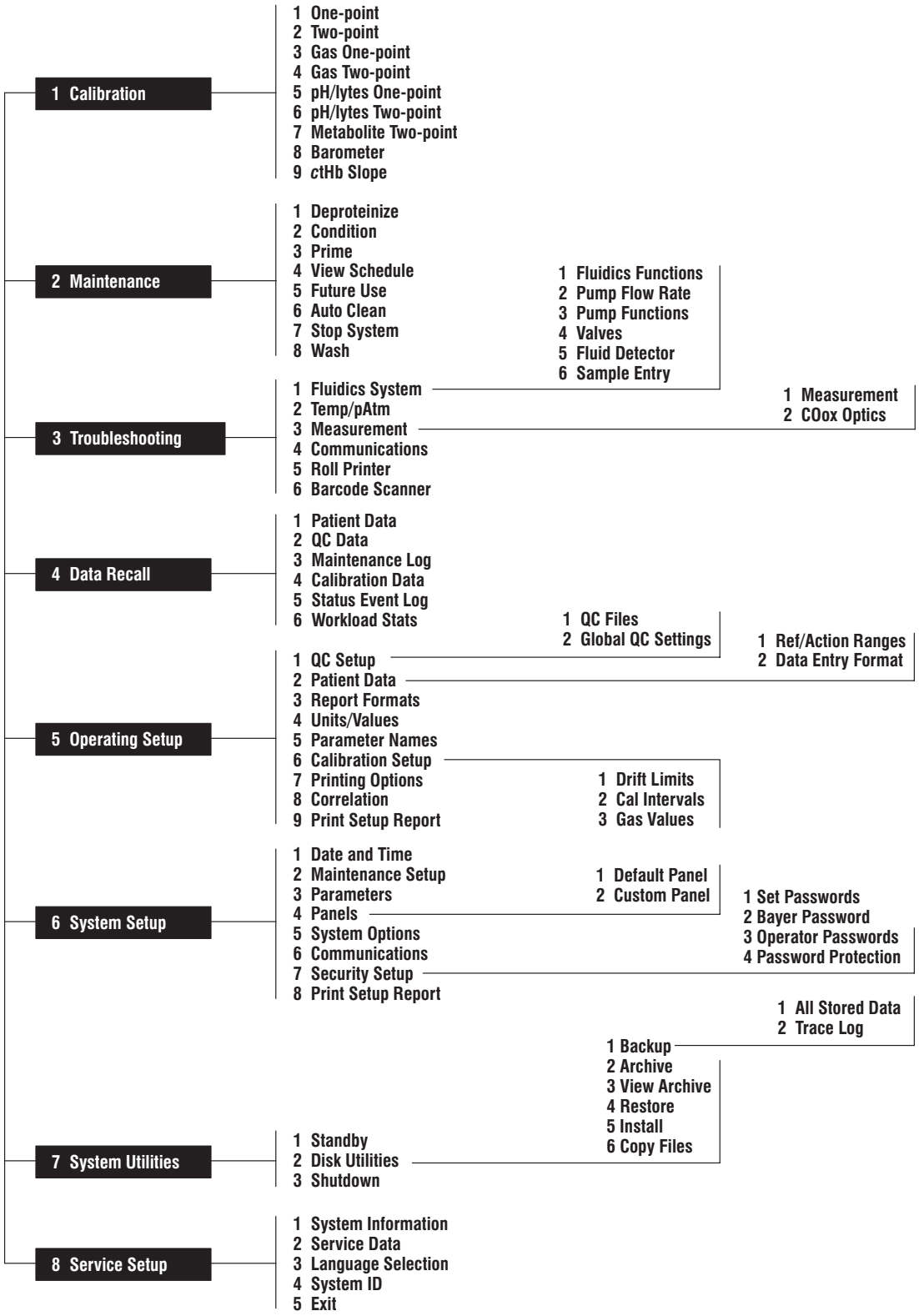
You move to the next menu by pressing the right arrow key or by pressing Enter. Again use the arrow keys to select the menu option you want. If dots (. . .) appear after the option, another menu exists for that option. If no dots appear after the option, the screen associated with the option appears when you press Enter. The following screen shows three levels of menus on the Menu screen:



The system automatically returns to the Ready screen if you do not press a key for at least 5 minutes. If you are using a troubleshooting menu option, the period of time before the system returns to the Ready screen extends to 30 minutes. The system does not automatically return to the ready screen when you access maintenance options.

Figure 1-11 shows a map identifying all the menu options available in the Menu mode. Menu options that are not available appear in lighter text on the screen.

Figure 1-11. Menu Map



Using Menu Codes

Use menu codes to quickly select menu options from the Main Menu on the Menu screen. To use menu codes, you press the numeric key for the menu option instead of using arrow keys and pressing Enter.

NOTE: For menu codes to work properly, begin only when the cursor is in the Main Menu.

Menu codes appear in the left margin, opposite procedures that require you to select menu options. The following example, which describes the steps to stop the system, shows how menu codes appear in the manual:

1. Stop the system from the Main menu:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop** and press **Enter**.

Menu Code
2 *7*

For this example, at the Main Menu you press **2** and then on the numeric keypad you press **7** to use menu codes.

NOTE: During some procedures, you may need to move to the Main Menu before you can press the menu code. The menu code for these procedures contains the phrase **(from the Main Menu)** to remind you to move to the Main Menu before pressing the menu code.

System Busy Icon

The system displays a clock icon to let you know the system is busy executing the last given command. For example, the clock icon may appear when the system searches the database to recall patient data from the search criteria screen. Once the patient records appear on the screen, the clock icon disappears from view.

Understanding the System Beeps

The system emits three types of beeps:

- short beep when you press the wrong key or type too many characters in a field
- long beep when the system detects a system error
- recurring short beeps when the system requires user action

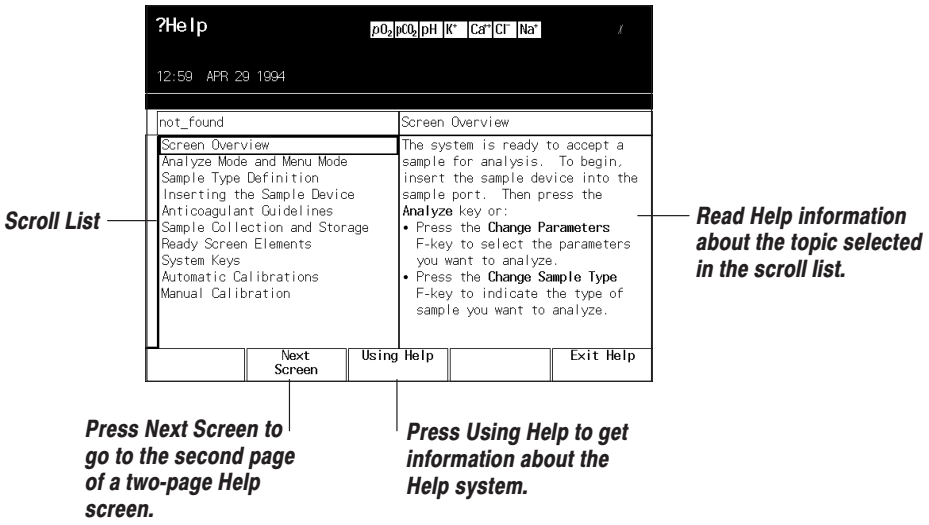
Using Help

Use the Help program to get information about your 800 system. You can access Help when the system is inactive or when the system is performing an operation, such as an analysis, a wash, or a calibration. When you access help during an operation, the Help screen appears and the operation continues in the background.

In the Analyze mode, press Help to access Help for the screen you are viewing. Analyze mode Help presents a general list of topics that are specifically related to the screen from where you press Help.

In the Menu mode, press Help to display a scroll list of Menu mode topics. Menu mode Help consists of an index of topics. Each topic describes a menu or menu selection. The topics do not vary from screen to screen.

The Help screens have two sides. The left side contains a scroll list of topics. You use the up and down arrow keys to select a topic. When you select a topic and press Enter, the right side displays information relating to the topic you choose.



You can press Exit Help to leave Help and return to the screen from which you accessed Help. If you press Help from the Analyze mode screen when the system is busy, you return to the current screen for the activity in progress.

Sample Information

This section describes sample requirements, collection procedures, and handling techniques for pH, blood gas, and electrolyte analysis. For a detailed review of sample requirements, refer to NCCLS Document C27–A, *Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls*.[1]

Since blood gases are typically the most sensitive of the parameters measured by the 800 system, the requirements and procedures described in this section are based on techniques appropriate to pH and blood gas analysis. The sample collection and handling guidelines described in this section are also suitable for electrolyte analysis.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Perform blood sample collection under proper medical supervision when selecting a site and performing the procedure. Ensure that the appropriate sample handling documents are in place.

Use sterile technique at all times to avoid infecting the sample site.

Limitations

The following indicate some of the procedural limitations encountered with blood gas analysis:

- Some auto-venting syringes contain sodium carboxymethylcellulose (CMC), a substance within the porous venting mechanism. CMC can dissolve into the sample, causing optical errors during CO-ox measurement. Optical errors may lower reported tHb and O_2Hb levels and elevate reported COHb. The recommended syringe is Bayer Diagnostics arterial sampling device because it uses a patented, non-exposed auto-venting design that does not affect the integrity of the sample.
- Interpret results from patients anesthetized with halothane or nitrous oxide cautiously. Patients anesthetized with these substances may have unreliable pO_2 values due to the reduction of halothane or nitrous oxide by the pO_2 electrode.[2]
- Avoid using sample collection devices containing EDTA, citrate, oxalate, and fluoride anticoagulants. These anticoagulants have a significant effect on blood pH and ionized calcium.

850 860 The following limitations apply to the 850 and 860 systems:

- Avoid hemolyzed samples, because they falsely elevate potassium levels due to intra-erythrocyte potassium levels.
- Avoid samples with elevated levels of salicylates, salicylate derivatives such as ibuprofen, and bromide (Br^-), because they falsely elevate chloride levels.
- Avoid samples contaminated with perchlorate (ClO_4^-), thiocyanate (SCN^-), iodide (I^-), and nitrate (NO_3^-), because they falsely elevate chloride levels.
- Avoid using excessive levels of heparin anticoagulants. Excessive levels of heparin anticoagulants cause calcium-heparin chelation and falsely decrease calcium levels.

860 The following limitations apply only to the 860 system:

- Avoid using sample collection devices containing fluoride/oxalate anticoagulants (the gray top tube). These anticoagulants have a significant effect on glucose and lactate.

Sample Sources

The 800 system can analyze samples obtained from the following sources:

Sample Source	Description
arterial blood	Arterial blood is commonly recommended for use in blood gas studies because it accurately reflects acid-base physiology and oxygenation status. Arterial blood is routinely obtained from the radial, femoral, or brachial arteries. Other sites can be used following catheterization or surgical procedures.
venous blood	Venous blood can provide satisfactory pH and pCO_2 values; however, venous pO_2 values may not be significant in routine clinical study without simultaneous study of arterial pO_2. Venous blood is routinely obtained from an antecubital vein using vacuum tube collection systems. Other sites can be used as necessary. Venous oxygen saturation values reported must be so labeled to ensure correct interpretation of the results.
mixed venous blood	Mixed venous (pulmonary artery) blood may be obtained from a pulmonary artery catheter after carefully clearing the catheter of infusion fluid. Take appropriate precautions to prevent mixing of pulmonary capillary blood with the pulmonary artery blood.

(Continued)

Sample Source	Description
expired gas	Expired gas samples may be obtained using a 10 mL syringe. When used in conjunction with blood gas samples, expired gas samples provide an assessment of gas exchange and oxygenation status.
capillary blood	Capillary blood, when carefully collected under the proper conditions, resembles arterial blood and can be used for blood gas studies if the sample limitations are understood.[1] Only small quantities of blood are required for capillary blood analysis. Capillary blood can be obtained from the heel, finger, or earlobe. The area chosen should be prewarmed or stimulated before the puncture to promote arterial circulation. The puncture should be deep enough to ensure that blood flow is free and rapid. Take appropriate precautions to minimize hemolysis, because potassium levels are falsely elevated in hemolyzed blood.

When collected correctly, arterial, venous, mixed venous, and capillary blood samples are also suitable for analyte determinations. For further information, refer to the Bayer Diagnostics brochure *Specimen Collection for Critical Blood Analyte™ Testing*.

Sample Collection Devices and Anticoagulants

You can use syringes, capillary tubes, and vacuum tubes to collect samples.

Syringes

⚠ **CAUTION:** Never use mineral oil or mercury in syringes since these substances may alter sample values and damage the system.

Collect blood in Bayer Diagnostics heparinized syringes or equivalent syringes to satisfy the requirements for blood gas analysis.

The recommended syringe for analyzing samples is the Bayer Diagnostics arterial sampling device. This sampling device uses a patented, non-exposed, auto-venting design that does not affect the integrity of the sample. Some auto-venting syringes contain sodium carboxymethylcellulose (CMC), a substance within the porous venting mechanism. CMC can dissolve into the sample, compromising sample integrity. CMC may lower the reported tHb and O_2Hb levels and elevate the reported COHb levels.

Capillary Tubes

CAUTION: Do not use clay-capped capillary tubes because the cut edges of a capillary tube can damage the sample port. Use only fire-polished capillary tubes to prevent damage to the sample port.

NOTE: To prevent hemolysis and maintain sample integrity, Bayer Diagnostics recommends using capillary tubes that do not contain mixing fleas.

Collect capillary blood using capillary tubes that contain the appropriate balanced heparin, such as Bayer Diagnostics Multicap balanced heparin capillary tubes. Take appropriate precautions to minimize hemolysis, because hemolysis falsely elevates potassium levels.

When you collect samples with a capillary tube, anticipate some sample loss due to clotting and capping. Fill the capillary tubes completely and mix the samples thoroughly.

Vacuum Tube Collection Systems

Collect venous blood using vacuum tubes containing lithium heparin. Fill the tubes completely and mix the sample by gently inverting the tubes.

Anticoagulants

CAUTION: Do not use anticoagulants such as EDTA, citrate, oxalate, and fluoride, since they significantly effect pH, ionized calcium, chloride, and metabolites.

Calcium-titrated (balanced) heparin and lithium heparin are the only acceptable anticoagulants for pH, blood gas, electrolyte, and metabolite analysis. Clotting and dilutional effects may be present if the sample collection technique is not performed correctly.

Sample Storage and Handling

The following conditions can cause erroneous results even when samples are collected correctly:

- metabolic activity in the sample that occurs between sampling and completion of analysis
- contamination of the sample by room air
- incorrect mixing of the sample before analysis

To minimize the errors these conditions can cause, use correct storage and handling techniques. You can minimize errors due to metabolic changes by analyzing samples as soon as possible after collection. This is particularly important for pO_2, glucose, and lactate values, because the sample consumes oxygen and glucose, and lactate is rapidly formed during storage. Lactate is produced by glycolysis and will increase while the sample is stored. Glycolysis is temperature dependent. Lactate increases approximately 0.1mM/hour at 4°C and 1.0 mM/hour at 37°C.* The rate of oxygen consumption depends on several factors:

- storage temperature
- white blood cell count
- reticulocyte count

If you cannot analyze samples within 10 minutes of collection, it may be appropriate to place the samples in an ice-water slurry, with the portion of the syringe containing the sample in contact with the ice-water slurry. You can store samples in an ice-water slurry for up to 2 hours without significant change in values for pH and pCO_2; however this will affect the K^+ values. Samples with elevated white blood cell or reticulocyte counts deteriorate more rapidly, and you should analyze them immediately.

You can minimize errors due to room-air contamination by preventing air from getting into the syringe. Immediately after drawing the sample, expel all the air from the syringe, securely cap the syringe, and thoroughly mix the sample. Never use corks as capping devices.

You can minimize errors due to incorrect sample mixing before analysis as follows:

- Roll a syringe between your hands and then gently invert the syringe several times.
- Gently invert a vacuum tube until the sample is homogenous.
- Thoroughly mix a capillary sample until it is homogenous.

Blood cells settle during storage. If the sample is not well mixed before analysis, the results obtained can be erroneous.

---

* Wandrup, Clinical Chemistry, 35/8, 1741, (1989).

Waste Disposal

Refer to *Emptying the Waste Bottle* in Section 3 for detailed instructions for handling the waste bottle and its contents.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

The waste bottle is disposable. You can autoclave the waste bottle before discarding it, but you cannot use it after autoclaving. After autoclaving, seal the waste bottle with the disposable cap and then discard the waste bottle.

Discard the waste bottle and its contents according to your laboratory protocol or hospital infection control procedure and local legal requirements. Refer to NCCLS Publication GP5–A, *Clinical Laboratory Hazardous Waste Guideline,* for detailed guidelines about disposal of hazardous waste.[3]

Reagents

This section describes the active ingredients, the intended use, the storage, and the handling instructions and the preparation instructions for the reagents used on the 800 systems.

WARNING Wear safety glasses, gloves, and laboratory coat when handling the reagents.

All reagents described in this section are for in vitro diagnostic use only. Bayer Diagnostics cannot guarantee the performance of the system when any of the following occur:

- Reagents other than those recommended are used.
- Reagents are used after the expiration date on the label.
- Reagents are not used or stored according to Bayer Diagnostics recommendations.
- Standard laboratory practices are not followed.
- The procedures in this manual are not followed.

Active Ingredients in Reagents

The reagents used on the 800 systems contain the following active ingredients:

Reagent	*Active Ingredients*
7.3/CO-ox Zero	140 mmol/L sodium 4.0 mmol/L potassium 100 mmol/L chloride 1.25 mmol/L calcium surfactant buffer
6.838 Buffer	100 mmol/L sodium 8.0 mmol/L potassium 70 mmol/L chloride 2.50 mmol/L calcium surfactant buffer
Wash G/L Zero	salts surfactant

(Continued)

Reagent	Active Ingredients
Cal G/L	10 mmol/L glucose 2.0 mmol/L lactate salts surfactant buffer
Cleaning Solution 1	cleaning compound
Cleaning Solution 2	cleaning compound
Conditioner	ammonium bifluoride (NH_4HF_2)
CO-oximeter Slope	dyes and viscosity adjuster
Deproteinizer	0.1N hydrochloric acid proteolytic enzyme

Material Safety Data Sheets (MSDS) can be obtained by contacting Bayer Diagnostics Customer Service.

Intended Use of Reagents

The reagents used on the 800 systems have the following intended uses:

Reagent	Intended Use
7.3/CO-ox Zero	7.3 reagent provides the calibration point for the one- and two-point pH and electrolyte calibrations and the zero calibration for the CO-ox module. 7.3 reagent is buffered to a pH of 7.382 at 37°C and is NIST traceable.
6.838 Buffer	6.838 Buffer provides the slope point for the two-point pH and electrolyte calibrations. 6.838 Buffer is buffered to a pH of 6.838 at 37°C and is NIST traceable.
Wash G/L Zero	Wash G/L Zero cleans the sample path after sample analysis and during wash sequences. Provides the calibration point for the two-point metabolite calibration.
Cal G/L	Cal G/L provides the calibration point for the one-point calibration and the slope point two-point metabolite calibration.
Cleaning Solution 1	Cleaning Solution 1, when alternated with Cleaning Solution 2, provides thorough cleaning of the reagent path.
Cleaning Solution 2	Cleaning Solution 2, when alternated with Cleaning Solution 1, provides thorough cleaning of the reagent path. **NOTE:** The system automatically cleans the reagent path, using one of these cleaning solutions, every 24 hours at 02:00 (default time). The cleaning cycle is followed by a two-point calibration.
Conditioner	Conditioner cleans and conditions the glass membranes of the pH and sodium sensors. Conditioner should be used regularly as part of the preventive maintenance for the system.
CO-oximeter Slope	CO-oximeter Slope provides the slope point for the tHb slope calibration.
Deproteinizer	Deproteinizer removes protein buildup from the sample path. Deproteinizer should be used regularly as part of the preventive maintenance for the system.

Storing Reagents

This section describes the storage instructions for the reagents used on the 800 systems.

CAUTION: Discard any reagent that is frozen. Do not thaw and use. The reagent composition is irreversibly altered when the reagent is frozen.

NOTE: Do not use any reagents beyond the expiration date. The expiration date for Bayer Diagnostics reagents indicates the last month of valid use for unopened reagents.

Reagent	Storage Instructions
7.3/CO-ox Zero	Store 7.3/CO-ox Zero upright at 4 to 25°C. Discard 7.3/CO-ox Zero 30 days after opening.
6.838 Buffer	Store 6.838 Buffer upright at 4 to 25°C. Discard 6.838 Buffer 60 days after opening.
Wash G/L Zero	Store Wash G/L Zero upright at 4 to 25°C. Discard Wash G/L Zero 60 days after opening.
Cal G/L	Store Cal G/L upright at 4 to 25°C. Discard Cal G/L 30 days after opening.
Cleaning Solution 1	Store Cleaning Solution 1 in the dark. The solution is light sensitive. Store Cleaning Solution 1 upright at 4 to 25°C. Discard Cleaning Solution 1 four weeks after opening.
Cleaning Solution 2	Store Cleaning Solution 2 in the dark. The solution is light sensitive. Store Cleaning Solution 2 upright at 4 to 25°C. Discard Cleaning Solution 2 four weeks after opening.
Conditioner	Store Conditioner at 4 to 25°C. Discard Conditioner 24 hours after opening.
Deproteinizer	Store Deproteinizer at 4 to 25°C. Activated material is stable for 24 hours when stored at 4 to 8°C. Discard Deproteinizer 24 hours after preparing.

Handling and Preparing Reagents

CAUTION: Discard any reagent that is frozen. Do not thaw and use. The reagent composition is irreversibly altered when the reagent is frozen.

Handle and prepare the reagents used on the 800 systems as follows:

Reagent	*Handling and Preparation Instructions*
7.3/CO-ox Zero	7.3/CO-ox Zero is ready to use. Invert the bottle several times to mix thoroughly before use.
6.838 Buffer	6.838 Buffer is ready to use. Invert the bottle several times to mix thoroughly before use.
Wash G/L Zero	WashG/L Zero is ready to use. Invert the bottle several times to mix thoroughly before use.
Cal G/L	Cal G/L is ready to use. Invert the bottle several times to mix thoroughly before use.
Cleaning Solution 1	Cleaning Solution 1 is ready to use. Invert the bottle several times to mix thoroughly before use.
Cleaning Solution 2	Cleaning Solution 2 is ready to use. Invert the bottle several times to mix thoroughly before use.
Conditioner	Conditioner is ready to use. Mix thoroughly before use.
CO-oximeter Slope	CO-oximeter slope is ready to use.
Deproteinizer	Prepare Deproteinizer according to the package directions. Allow the solution to sit at room temperature for 10 to 15 minutes or until the powder dissolves. When the powder dissolves, invert the vial several times to ensure that the solution is thoroughly mixed before aspirating it into the system.

NOTE: Do not tighten or remove the bottle cap on any on-board reagent, or attempt to mix the contents of one bottle with another. The bottle caps are adjusted to ensure correct reagent flow.

Calibration Gases

The 800 system requires two gases to calibrate the pCO_2 and pO_2 sensors, Cal Gas and Slope Gas.

Cal Gas provides the calibration point for both pCO_2 and pO_2 sensors during one- and two-point calibrations. Cal Gas contains 5.00 ±0.03 mol% carbon dioxide and 12.00 ±0.03 mol% oxygen balanced with nitrogen. Cal Gas is NIST traceable.

Slope Gas provides the slope point for pCO_2 and pO_2 sensors during two-point calibrations. Slope Gas contains 10.00 ±0.03 mol% carbon dioxide balanced with nitrogen. Slope Gas is NIST traceable.

WARNING Compressed gas tanks can explode if mishandled. To prevent personal injury or damage to the tank, observe the following precautions when handling the tanks:

- Secure tanks to a wall, a bench, or the floor, or place them in a tank base support stand.
- Use calibration gases only for the calibration of clinical and research instruments. Do not dispense these gases for drug use.
- Do not drop tanks, do not allow tanks to strike each other, and do not subject tanks to other strong shocks.
- Do not drag, roll, or slide tanks. Use a suitable hand truck to move tanks.
- Do not tamper with safety devices in regulators or tanks.
- Do not puncture the tanks. Tank contents are under pressure.
- Do not use or store tanks near heat or open flame.
- Do not expose tanks to temperatures above 54°C (130°F) because contents can vent or explode.
- Do not dispose of tanks in a fire or an incinerator. Follow the disposal instructions printed on the tanks.

Calibration

Calibration is the process of testing and adjusting the electronic signal from a sensor in response to a known concentration of a calibration solution or of a gas standard. Calibration establishes a relationship between the electrical output of a sensor and the concentration of the analyte measured by the sensor. Electronic drift and normal sensor aging can cause variations in electronic signals.

The relationship between the sensor signal and the concentration of a measured analyte (or its logarithm) is linear. A straight line calibration curve can be determined by measuring the sensor signal from two different reagents of known concentration. Each measurement defines one point on the calibration curve. Calibration offset (y-intercept) and slope are calculated using the measured signal and known concentration as established on the calibration curve. The concentration of an unknown sample (patient or QC) is determined by comparing its generated signal during measurement to the established calibration curve. The 800 system performs calibrations and sample measurements of pH, blood gases, electrolytes, and metabolites at 37.0 ± 0.15°C, and hemoglobin and its derivatives at 37.0 ± 0.35°C.

The 800 system uses the following calibrations for each measured parameter:

- one-point calibration

  A one-point calibration adjusts either the offset or the slope drift for a parameter by measuring one reagent of known concentration.

  NOTE: The metabolite one-point calibration measures the slope drift.

- two-point calibration

  A two-point calibration adjusts both the offset and the slope drift for a parameter by measuring two reagents of known concentration.

The following sections describe specific calibration features of the 800 system.

Automatic Calibrations

The 800 system automatically performs one- and two-point calibrations. The system provides two options for determining when automatic calibrations occur. They are fixed time and flexible time.

Fixed time performs calibrations at regular intervals. You define the intervals in setup. The system default interval for one-point calibrations is 30 minutes, and the default for two-point calibrations is 120 minutes.

Flexible time performs calibrations at various intervals. The system uses an algorithm to determine the number of minutes between calibrations. This algorithm is based on sensor status and the change in drift values from previous calibrations. Calibrations are performed at intervals necessary to avoid excessive drift to the sensor that is experiencing the fastest rate of drift. The default time for the minimum time between calibrations is 10 minutes. You can define the minimum time between intervals for one-point calibrations in setup. The minimum time for two-point calibrations is four times the value entered for one-point calibrations. Refer to *Selecting Calibration Frequency and Automatic Repeat* in Section 5 for more information about defining the time interval for automatic calibrations.

The system indicates that an automatic calibration is pending 5 minutes before the calibration is scheduled and continues to display the time remaining until the calibration starts. The sample door closes when a calibration starts. The timing bar indicates the approximate time to calibration completion. During a calibration, you cannot access the Menu mode.

You can defer or interrupt calibrations to analyze samples. You can defer automatic calibrations for up to 30 minutes. After 30 minutes, the system is not in calibration. The system then starts the required calibration automatically. The system does not accept samples until the required calibration finishes.

Glucose Biosensor Calibrations

860

In addition to the regularly scheduled one-and two-point calibrations, the 860 system has a metabolite recal option. The metabolite recal option allows the system to perform an automatic one-point metabolite calibration to minimize within run drift during rapid sampling. Metabolite recal is particularly useful in controlling within run drift for newly installed glucose biosensors. Turning off the metabolite recal option will increase sample throughput time. With metabolite recal off, glucose is calibrated only at the regularly scheduled one and two-point calibrations.

Metabolite recal also decreases within run glucose drift when running many replicates of QC material. Turning off the recal option does not significantly affect QC sample results, as most QC samples are limited to 6 replicates in a run. Individual laboratories should determine if glucose QC recovery is acceptable with metabolite recal off.

Metabolite recal calibrates the glucose biosensor under two sets of criteria in a cyclical manner. First, the system uses an algorithm to determine the frequency of samples. If two consecutive QC samples or a combination of three QC and patient samples are analyzed at an average rate of 4 minutes or less between samples, the system begins a metabolite one-point calibration at the completion of the analysis. If a regularly scheduled one- or two-point calibration is due, the system performs the scheduled calibration instead.

The system displays a status message indicating that a one-point metabolite calibration is due at the completion of the sample analysis. The glucose sensor is inactive until the calibration is successfully completed. You cannot defer this calibration.

Second, after completing the calibration, the system sets a 5 minute timer. If no samples are run within this period, the system performs another metabolite recal at the end of 5 minutes. You can defer this calibration by running samples.

If two consecutive QC samples are run within 4 minutes of each other during the 5 minute timer or when the second calibration is completed, the system begins the calibration cycle again by returning to the first set of criteria described above.

You can interrupt either calibration, but the glucose sensor is inactive until the sensor is successfully calibrated.

Manual Calibrations

You can perform calibrations manually from the Analyze mode when the system is not analyzing samples and from the Menu mode. You perform calibrations from the Analyze mode by pressing Calibrate. You perform calibrations in the Menu mode by selecting Calibrations from the Menu screen.

tHb Calibration

The CO-ox module is calibrated for zero and slope. The zero is performed automatically during the 7.3 Buffer calibration step of a one- and two-point calibration. You must introduce the reagent that the system uses to measure the slope. The default and maximum interval for a tHb slope calibration is 30 days. The minimum interval between slope calibrations is 1 day.

Barometer Calibration

The atmospheric pressure is important to ensure accurate gas calibration. The 800 system contains an internal barometer. Check the barometer calibration daily. Measure your laboratory's current atmospheric pressure using a high-quality barometer that has been calibrated to, or directly measures, actual atmospheric pressure. Enter the atmospheric pressure into the 800 system to calibrate its internal barometer. Refer to *Checking the Barometer* in Section 3.

Calibration Results

The system displays calibration results on the screen and updates them continuously until the parameters reach endpoint. The system then adjusts the values to match the theoretically expected results. The screen displays the measured and the drift values for each calibrated parameter. If a sensor does not reach endpoint within 90 seconds, the parameter value appears on the screen with asterisks and the message D5 No Endpoint. The sensor is not in calibration until the system completes a successful calibration.

Calibration Drift Limits

Variation in the electronic signal generated by sensors in response to samples and normal sensor aging can cause calibration drift. You can define acceptable calibration drift limits for the 800 system. If the detected changes to the offset and the slope values are larger than defined, the system informs you that drift limits are exceeded. If the drift for a sensor is greater than defined, that sensor is not in calibration. Until a successful calibration completes, all subsequent measurements indicate the not-in-calibration condition on the screen and on the printed reports.

Repeating Calibrations with Calibration Drift

The system automatically repeats a calibration when drift limits are exceeded if the auto repeat or flexible-time options are defined for the system. The system repeats up to two calibrations to calibrate a sensor or to zero the CO-ox module. It repeats the calibration only for the sensor with excessive drift, and prints a calibration report for each repeat calibration. If connected to an LIS, it sends the calibration data to the LIS. If a sensor fails two repeat calibrations, the sensor is disabled and not available to measure samples. The screen and printed results identify the disabled sensor. When a sensor is not available because of excessive drift, the other sensors are not affected.

Reporting Results with Calibration Drift

You can specify whether you want to report sample results when calibration drift limits are exceeded. If you do report results with calibration drift, the system permanently logs this exception in the status log. Refer to *Defining Drift Limits* in Section 5.

Recalling Calibration Data

You can view, print, and transmit stored calibration data using the Recall option. You cannot edit calibration data. You can search for the data by calibration type or calibration date and time.

Quality Control

Quality control (QC) procedures are part of an overall quality assurance program. Quality control testing evaluates system performance for imprecision and inaccuracy to ensure that results of patient samples are accurate and reliable. Imprecision is a measure of random error and variability. Random errors are sporadic and do not show trends or shifts of values around the mean. Inaccuracy is a measure of bias or systematic error. Systematic errors show trends or shifts of values around the mean.

The following are possible causes of systematic errors:

- contaminated calibrators
- improper calibration
- inaccurate barometer calibration
- sensor problems or aging of membranes
- electronic noise
- improper storage and handling of QC materials

U.S. federal regulations state that each laboratory must establish QC procedures to document and to evaluate system performance that ensure the accuracy and the reliability of patient results and reports.[4] QC procedures must also describe remedial actions when the measured values for QC materials exceed established limits. Your institution may also need to fulfill additional country, state, and local requirements. Analyzing QC materials and evaluating the results using predefined criteria is part of an overall quality assurance program. A well-designed quality assurance program also includes written protocols that describe patient preparation and identification, specimen collection and handling, sample analysis, system calibration and maintenance schedules, and reporting patient results.

Quality Control Materials

Quality control materials are substances that have known expected values that cover the clinically significant range for each parameter.

To monitor system performance and to chart any trends, Bayer Diagnostics recommends that you analyze controls as follows:

For these parameters . . .	Analyze at least . . .
pH, pO_2, pCO_2	one sample of control at least once during each eight–hour shift using at least two levels of control during each day of testing.
Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate	two levels of control at least once every 24 hours.
tHb	two levels of control at least once during each eight–hour shift.

If your established QC program requires more frequent use of controls, then follow those procedures. Treat all quality control materials as you do patient samples.

Monitoring the results of QC analyses can alert you to possible system performance problems and may help you predict sensor failure. More frequent use of controls may be required to evaluate system performance during troubleshooting operations.

In addition to daily QC monitoring, participation in interlaboratory QC survey programs lets you compare your system performance with systems in other laboratories. Participation in interlaboratory QC survey and proficiency testing programs can identify systematic errors not detected by intralaboratory QC testing alone.

Quality control results may differ from one system to another due to sample handling, system imprecision, and laboratory environment. Therefore, your institution should establish its own expected results range and action range for each parameter using data collected from determinations made over at least 20 separate runs.[5] The mean values established by your institution should fall within the ranges provided by the manufacturer of the QC material for each parameter. To establish expected result and action ranges for new lots of QC materials, analyze the new QC materials in parallel with existing materials.

Quality Control Statistics

Statistics are used to evaluate QC results and establish the probability of the accuracy (confidence limits) of a given measurement. These statistics are used to determine if the system is performing as expected and if patient data should be accepted or rejected.

Quality control limits are established by calculating the mean and standard deviation (SD) from multiple measurements of the QC material.[5] Typical QC limits use ± 2 SD or ± 3 SD where there is approximately a 95.5% probability that a result is within the 2 SD range and approximately a 99.7% probability that a result is within the 3 SD range when the system is performing as expected. QC results are compared to the established limits to evaluate system performance. If the results are within the established limits, the system is considered to be performing properly and patient results may be accepted. If the results are outside the established limits, the system may have problems that should be investigated before reporting patient results. Take corrective action according to procedures established for your laboratory. Bayer Diagnostics recommends that you do the following:

- Ensure that the calibration reagents and QC materials are not expired or have not deteriorated. Visible signs of deterioration include color changes or cloudiness of the reagents or QC materials.
- Ensure that you followed the operating procedures recommended in this manual.
- Ensure that you handled and sampled the QC materials according to the procedures recommended by the manufacturer.
- Rerun the QC materials.

QC File Information

You can define up to 12 QC files on an 800 system. Each file can store up to 150 QC sample reports. The file maintains the month-to-date and lot-to-date statistics, which include the mean, standard deviation, and coefficient of variation. After a QC file reaches 150 reports the system deletes the oldest report in the file to make room for a new QC report.

Each QC file contains the following information:

Parameter	*Description*
file number	the number that identifies the file
QC ID	the code that identifies the QC material assigned to the file
level	the level of the QC material
lot number	the manufacturing lot number of the QC material
expiration date	the last date you can use the QC material
expected (target) mean	for each parameter, the expected average measured value of the QC samples

(Continued)

Parameter	Description
expected (target) range	for each parameter, the measurement limits above and below the mean where the majority of the QC samples are expected to fall
action range	for each parameter, the measurement limits above and below the mean requiring immediate action
sample results	the results for each parameter, the QC sequence number, and the analysis date and time
cumulative statistics	for each parameter, the mean, standard deviation, coefficient of variation, and number of samples analyzed

Bayer Diagnostics Service Representatives use File 13 to store data during service calls. File 14 is the discard file. The system stores QC results in File 14 that you discard at the end of QC analysis. You can move and change the status of a file in File 14 using Recall. Refer to *Recalling QC Data* in Section 2.

The system assigns a sequence number to each QC sample in the order that you analyze the samples. QC sequence numbers are independent of the QC file information. Sequence numbers run from 100 through 99999 and then repeat.

Identifying QC Files Automatically

If the auto ID option is on, the 800 system automatically identifies the QC sample results and selects the appropriate QC file to store the results. The system compares the results for pH and pCO_2 to the target ranges defined for each parameter. If the results for these parameters are within the target ranges, the 800 system selects the QC file in which to store the results and prompts you to confirm the file assignment. If the results are not within the action range, or if one or both of the pH or pCO_2 sensors are not calibrated or are not available, the system does not select a QC file. You can then select a QC file for the results. Refer to *Selecting Automatic QC File Assignment* in Section 5 to use this option.

Accepting QC Results Automatically

If the 800 system is connected to an LIS or a data management system, you can use Auto Accept to have the system automatically accept QC results and send them to the LIS or data management system. You can then accept, reject, or discard results at the LIS or data management system. Refer to *Selecting Automatic Acceptance of QC Results* in Section 5 to use this option.

Sending QC Results Automatically

The system can automatically transmit QC results to an LIS or a data management system when analysis is complete. Refer to *Selecting Automatic Transmission of QC Results* in Section 5 to use this option.

Recalling QC Data

You can view, edit, print, and transmit stored QC data using the recall option. You can search for the data by file number, lot, level, analysis date, and analysis time. You can view and print the following QC data:

- individual QC sample reports
- Levey-Jennings charts
- statistical summary reports

Refer to *Recalling QC Data* in Section 2.

You can recall QC data for the previous month before you analyze the first QC sample of the current month. After you analyze the first QC sample of the current month, you can view the previous month's QC data by archiving the previous month's QC data and viewing the archived QC data. Refer to *Archiving QC Data* and *Viewing Archived QC Data* in Section 5.

Levey-Jennings Charts

The 800 system provides Levey-Jennings charts, which are visual representations of QC performance. Levey-Jennings charts allow rapid detection of results that fall outside the established QC limits. Additionally, Levey-Jennings charts let you observe trends or shifts in QC values, which may signal system performance problems, even when the actual values fall within the established limits.

Refer to *Viewing and Printing Levey-Jennings Charts* in Section 2 to view and print Levey-Jennings charts for the current month's QC data.

You can view and print Levey-Jennings charts for the previous month before you analyze the first QC sample of the current month. After you analyze the first QC sample of the current month, you can print the previous month's Levey-Jennings charts only by archiving the previous month's QC data and then printing Levey-Jennings charts of the archived QC data. Refer to *Archiving QC Data* and *Viewing Archived QC Data* in Section 5.

Statistical Summary Reports

Statistical summary reports present the month-to-date and lot-to-date mean, standard deviation, coefficient of variation, and number of samples for each QC file. You can print a statistical summary report for each current QC file using the recall option. Refer to *Recalling QC Data* in Section 2.

At 0200 on the first day of the month, the system automatically prints a final statistical summary report for each QC file. If you change the time of the Auto Clean, the system prints the final statistical summary reports at that time on the first day of the month. Review your QC files before the last day of the month to ensure that the QC files are updated.

After you analyze the first QC sample of the current month, you cannot view or print the previous month's QC data on the system. You can archive the previous month's QC data and then print the statistical summary reports for the previous month. Refer to *Archiving QC Data* and *Viewing Archived QC Data* in Section 5.

Archiving QC Data

Archiving QC data saves the previous month's QC file results and statistics on a diskette. You can use this diskette to retrieve historical QC data, which you can view or use to print QC reports and statistical summary reports. You cannot edit or restore data from an archive diskette.

Archiving can be done before or after you analyze the first QC sample of the current month. When you analyze the first QC sample of the current month, a message box reminds you to archive the previous month's QC data.

After you analyze the first QC sample of the current month, you cannot view or print the previous month's QC data on the system. However, the previous month's QC data is retained on the hard disk until the end of the current month. You can archive this data one or more times during the current month and then view or print the archived data. At the end of the current month, the system permanently deletes the previous month's QC data.

In addition, you can view, edit, print, or transmit the previous month's QC data before you analyze the first QC sample of the current month. Refer to *Recalling QC Data* in Section 2.

Calibration Verification

Calibration verification is the measurement of calibration materials to verify that the calibration of the system has remained stable throughout the patient reportable range established for your system.[4] While routine QC testing evaluates system performance in the clinically significant range, calibration verification periodically checks the upper and lower limits of the reportable range where patient results occasionally fall.

Use Calibration Verification Material (CVM) to comply with current federal, state, and local requirements. Your institution should establish its own criteria to evaluate system performance when verifying calibration.

Verify calibration in the following circumstances:

- when you change reagent lot numbers, unless your laboratory can demonstrate that the patient reportable range and the control values are not adversely affected
- when you perform major preventive maintenance or replace critical components on your system
- when controls reflect unusual trends or are consistently outside your laboratory's acceptable limits
- when a new system is installed

Analyte Performance Verification

Laboratories introducing new test systems or methods should verify or establish performance specifications before reporting patient results using the new test system or method. The APV℠ process that Bayer Diagnostics offers provides you with data for performance characteristics that you must verify to meet CLIA requirements. US federal regulations require that each laboratory demonstrates performance specifications comparable to the manufacturer for the following characteristics:[4]

- accuracy
- precision
- reportable range verification and calibration verification
- reference range verification

The APV process also provides data for the following performance characteristics that may not be required to meet CLIA requirements:

- control verification
- sensitivity

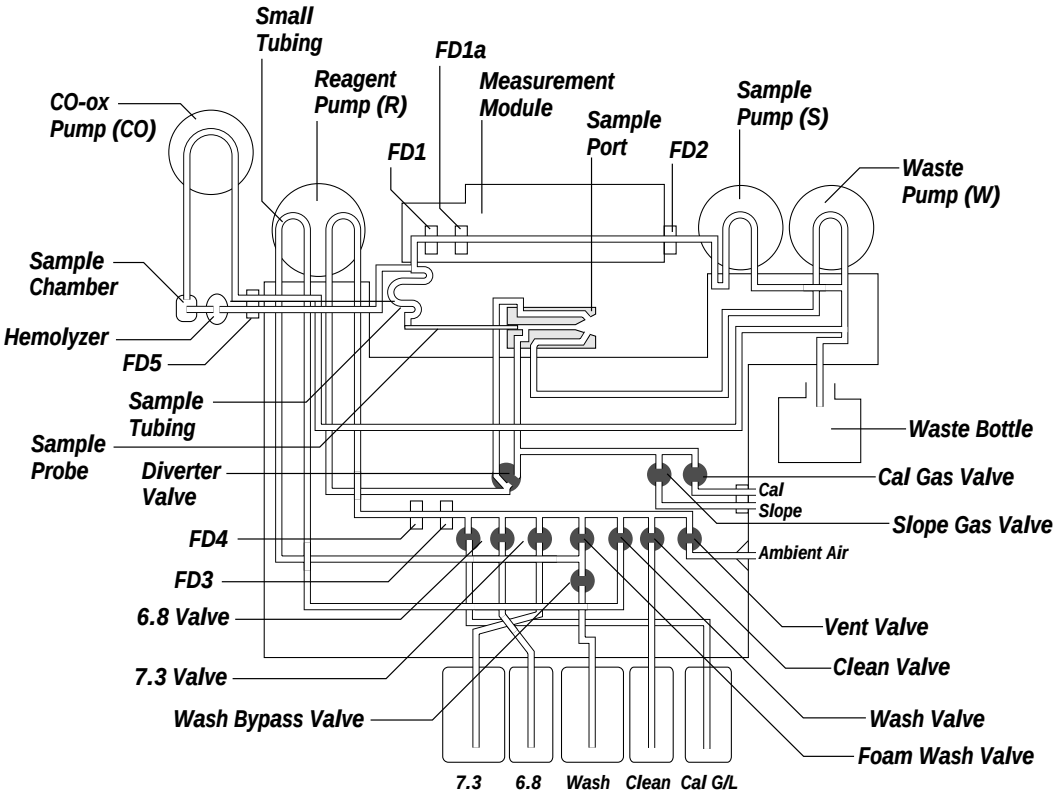
You can also obtain correlation data by parallel testing of patient samples that span the reportable ranges on the new system and on the existing system or method. Results from the new system are plotted against the existing system or method. Typically, linear regression and least squares evaluation are used to compare results. The slope and intercept of the regression line can be used to match the results of the new system to an existing system or method. Refer to Appendix G, *Correlation Adjustment.*

Refer to the *Analyte Performance Verification Interpretive Guide*, which is provided by Bayer Diagnostics during the APV process, for more information about the APV process.

Sequence Diagrams

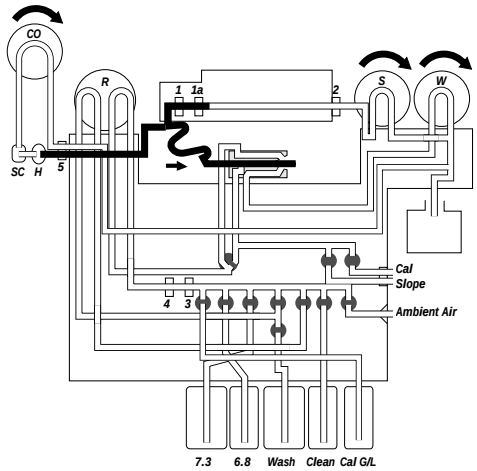
The following system sequence diagrams illustrate the flow of liquids and gases through the 800 system. Figure 1-12 identifies the components of the system sequence diagrams for the base model with a CO-ox module. The legend in Figure 1-12 describes the conventions used in the diagrams.

Figure 1-12. System Components

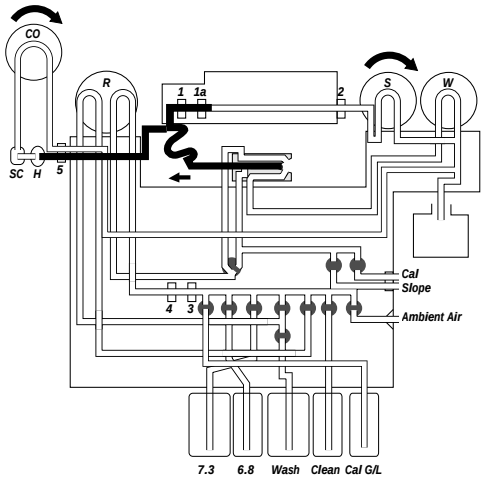


·····	pathways containing air
- - - - - - -	pathways containing gas
———	pathways containing liquid
———	pathways containing foam wash
	pump movement
	alternating pump movement
	an open valve

Sample Sequence

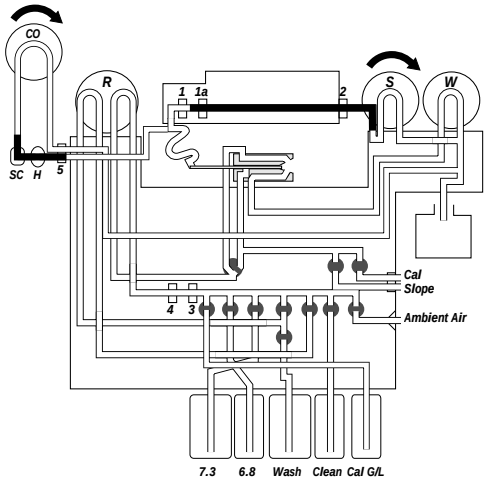


1. The sample door closes and determines the sample type and the probe extends accordingly. The waste and sample pumps start, and the sample moves to fluid detector (FD) 1 and 1A. The CO-ox module pump moves part of the sample to FD5.

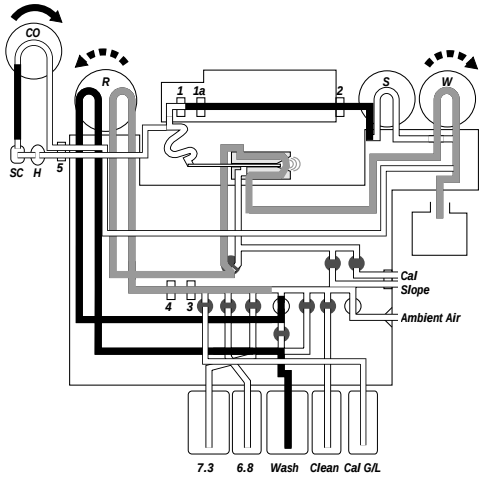


2. The probe retracts. The sample door opens and the system prompts you to remove the sample device. When the sample device is removed, the door closes over the sample port.

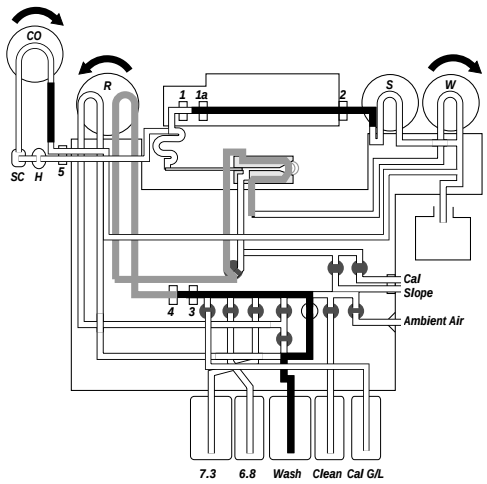
(Continued)



3. The sample pump moves the sample to fluid detector 2, pauses for one second, and then moves the sample until the trailing edge is detected at fluid detector 1. The CO-ox sample moves through the hemolyzer and the sample chamber. All parameters are measured.

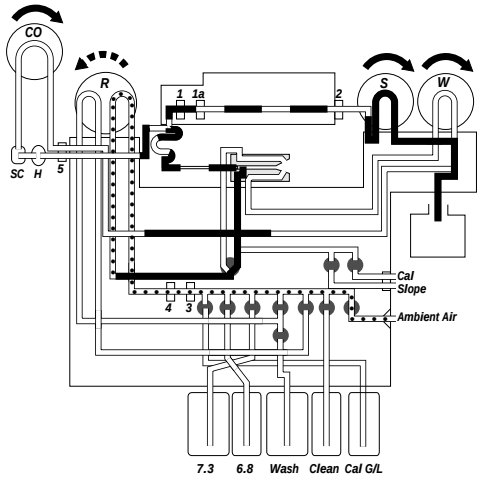


4. The sample port and reagent manifold are washed while the measurement is being made. The foam wash and vent valves open, the reagent pump starts, and foam wash moves to the outer sample port. The reagent pump stops, the waste pump starts, and the foam wash is removed from the sample port. This sequence repeats four times and is followed by a solid wash segment.

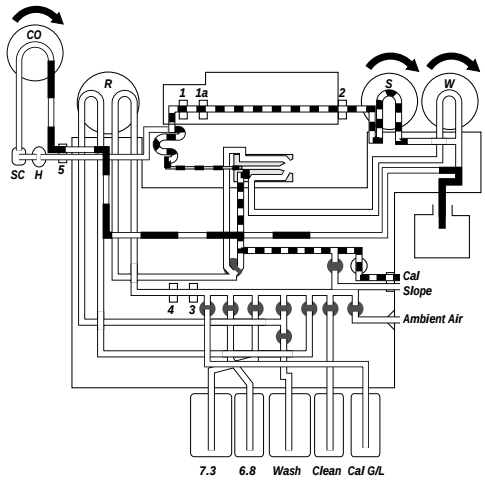


5. When the measurement completes, the sample probe fully retracts. The reagent pump starts and moves the remaining foam wash to the outer sample port. The reagent pump stops, the waste pump starts, and the wash is removed from the sample port. This cleans the capillary seal and the measurement module.

(Continued)



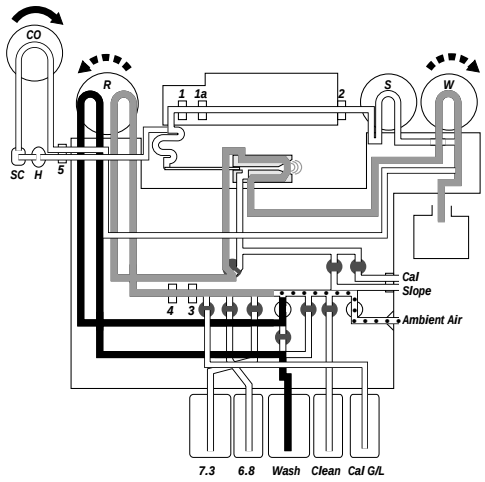
6. After all of the foam wash is removed, the reagent pump starts, the wash bypass, and vent valves open, and the remaining solid wash segment moves to the inner sample port. After the solid wash segment reaches the inner sample port, the reagent pump stops and the sample pump empties the wash from the sample port area. The reagent pump introduces another solid wash segment into the sample port. When the CO-ox module is attached, wash segments are split at the sample connector, so the CO-ox sample path is thoroughly cleaned. This sequence repeats 11 times to create wash segments that thoroughly clean the measurement module. The waste pump is on.



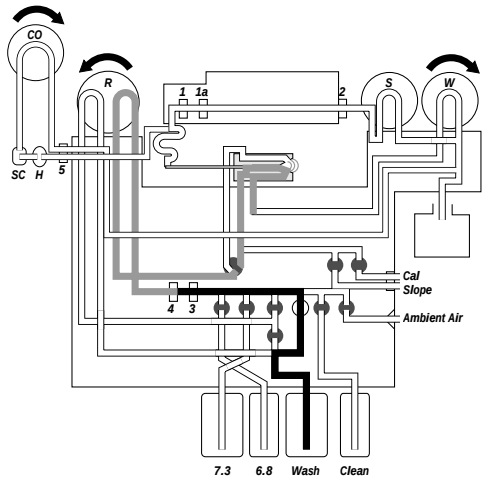
7. After the wash segments pass through the measurement module, the Cal gas valve opens and the sample pump starts to move Cal gas into the measurement module. The CO-ox pump moves the remaining wash segments to the waste bottle. The waste pump is on to prevent a bubble from forming at the sample port. The sample door opens when the sequence completes.

Wash Sequence

The following steps describe the activities that take place when you initiate a wash sequence by selecting Wash or Cancel.

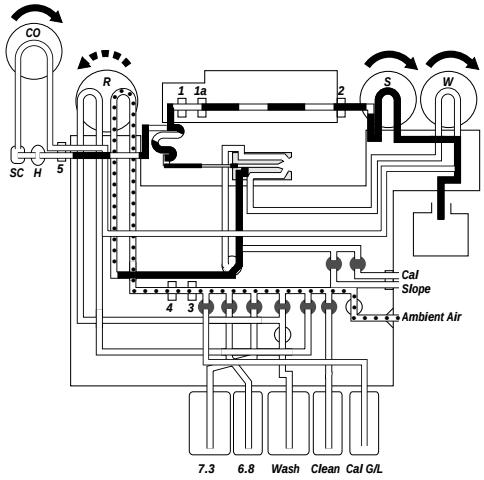


1. The sample door closes and the probe fully retracts. The foam wash and vent valves open, the reagent pump starts, and foam wash moves to the outer sample port. The reagent pump stops, the waste pump starts and the foam wash is emptied from the sample port. This sequence repeats four times and is followed by a solid wash segment.

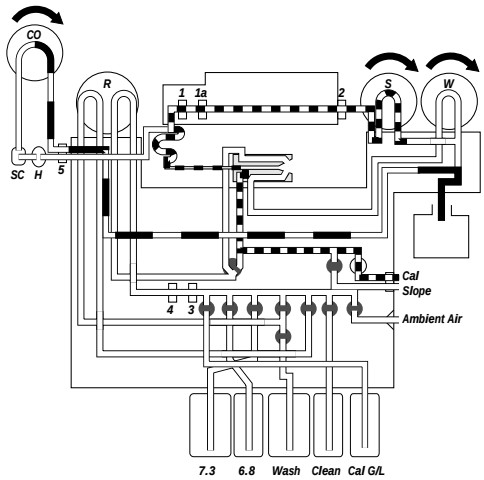


2. The sample probe fully retracts, the reagent pump starts, the diverter valve opens, and the remaining foam wash moves to the inner sample port. The reagent pump stops, the waste pump starts, and the wash is removed from the sample port. This cleans the inside of the capillary seal and the measurement module.

(Continued)



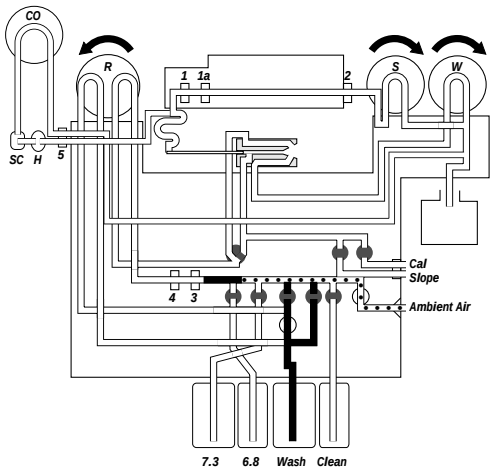
3. The reagent pump starts, wash bypass, and vent valves open, and the remaining solid wash segment moves to the inner sample port. The wash bypass valve is open while the reagent pump is on to prevent leakage from the foam wash valve. After the solid wash segment reaches the inner sample port, the reagent pump stops and the sample pump moves the wash from the sample port into the measurement module. The reagent pump introduces another solid wash segment into the sample port. This sequence repeats 11 times to create wash segments that thoroughly clean the measurement module. The waste pump is on.



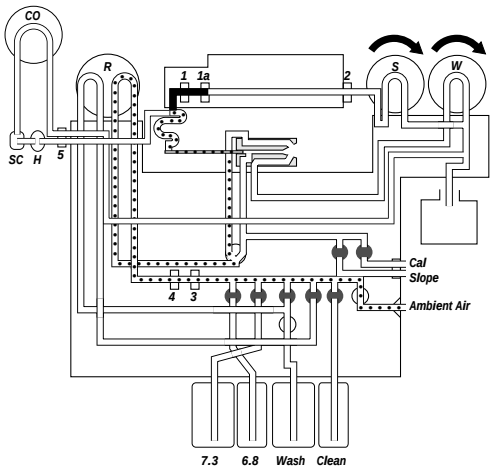
4. After the wash segments pass through the measurement module, the Cal gas valve opens, the sample pump starts, and Cal gas moves to the measurement module. The CO-ox pump moves the remaining wash segments to the waste bottle. The waste pump is on to prevent a bubble from forming at the sample port. The sample door opens when the sequence completes.

One-Point Calibration Sequence

The following steps describe the activities that take place during a one-point calibration.

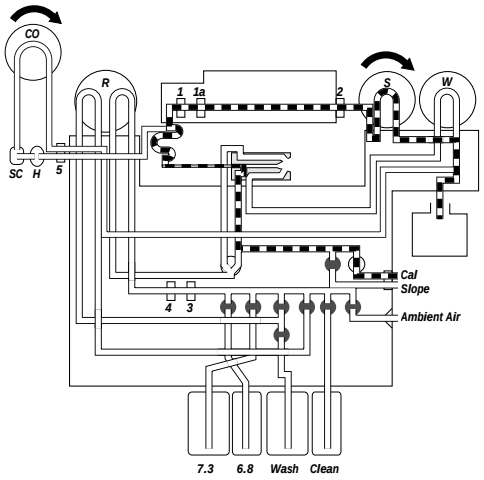


1. The sample door closes and the probe fully retracts. The reagent pump starts, the wash valve opens, and a wash segment is introduced into the reagent manifold. The sample and waste pumps start. The wash valve closes. The vent valve opens.

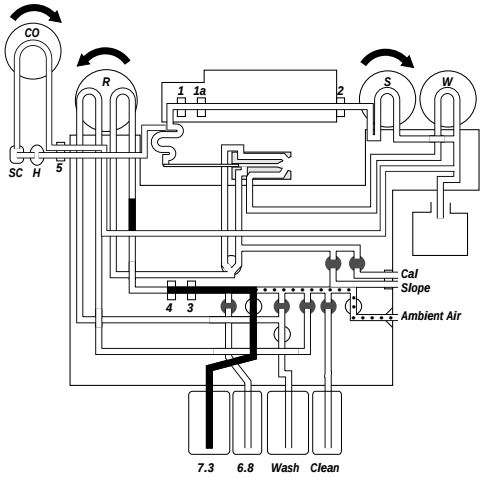


2. The vent valve, wash bypass valve, and diverter valve open. The sample pump and waste pump start. The wash segment moves through the measurement module to wet the sample path and allow humidification of the gas sensors.

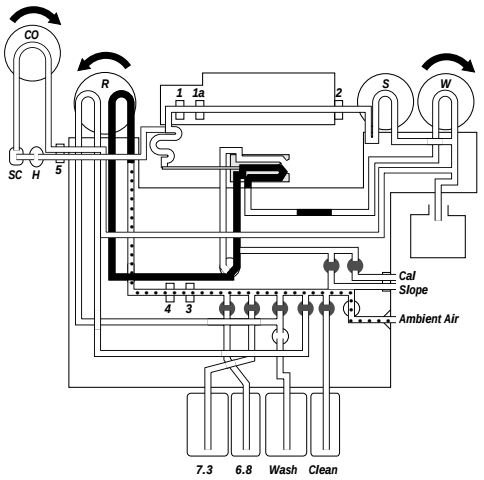
(Continued)



3. After the wash segment moves through the measurement module, the Cal gas and diverter valves open and Cal gas flows into the inner sample port. The sample pump aspirates the Cal gas at a controlled rate through the measurement module where pO_2 and pCO_2 are measured. The CO-ox pumps starts to prevent contamination of the sample connector by ambient air.

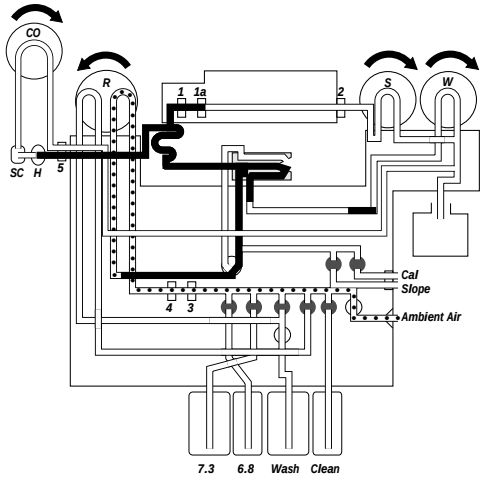


4. After the gases are measured, the 7.3 valve, wash bypass valve, and diverter valve open. The reagent pump moves a 7.3 reagent pre-segment and main segment from the reagent manifold toward the inner sample port. The sample pump is on.

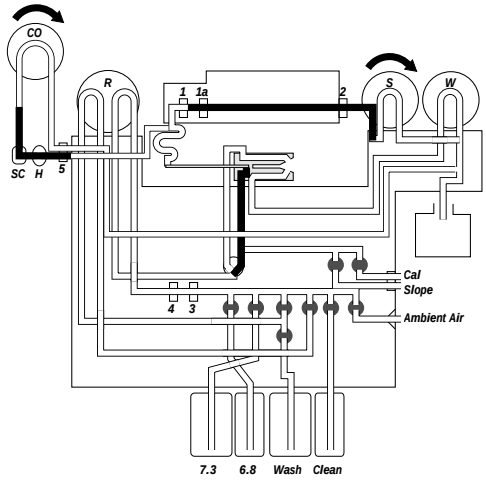


5. The reagent and waste pumps remain on. The pre-segment moves through the sample port into the waste and removes any residual reagent in the manifold.

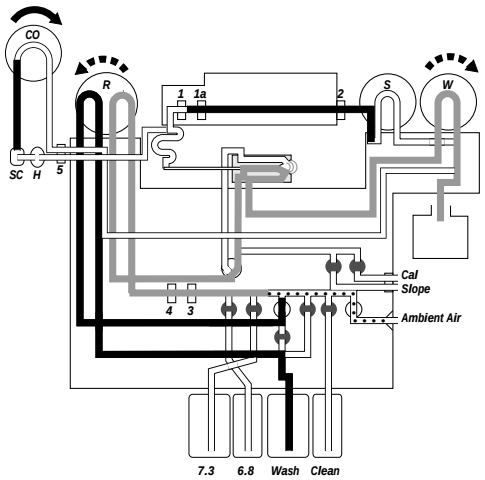
(Continued)



6. The main segment moves toward the sample port. When the main segment reaches the sample port, the sample pump starts and moves the segment to the measurement module until it is detected by fluid detector 1 and 1A. The CO-ox module pump moves the 7.3 reagent to FD5. The waste pump starts.

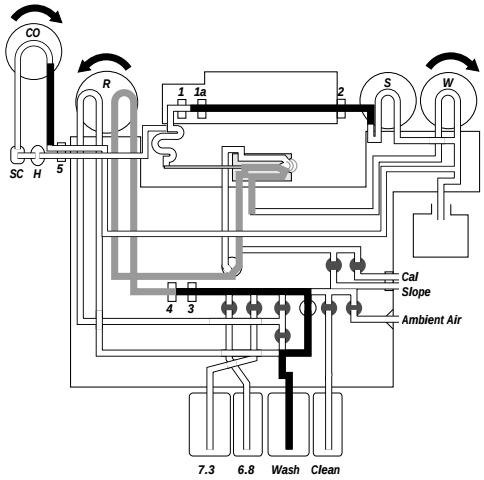


7. The probe extends and the main segment moves until the trailing edge is at fluid detector 1. The pumps stop and the analytes are measured. The CO-ox zero calibration is performed.

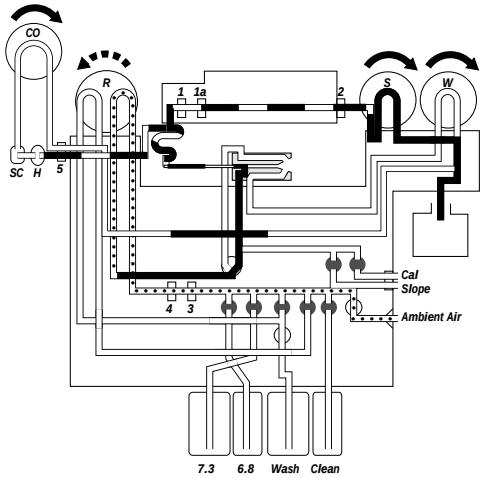


8. The sample port and reagent manifold are washed while the measurement is being made. The probe fully retracts. The foam wash and vent valves open, allowing the wash solution to become segmented with air, creating foam wash. The reagent pump starts and moves foam wash to the inner sample port. The reagent pump stops, the waste pump starts, and the foam wash is emptied from the sample port. This sequence repeats four times and is followed by a solid wash segment.

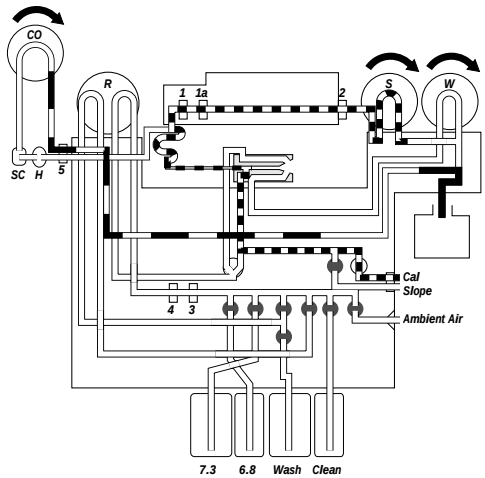
(Continued)



9. When the measurement completes, the reagent pump starts and moves the remaining foam wash to the inner sample port. The reagent pump stops, the waste pump starts, and the wash moves from the sample port to the waste. This cleans the inside of the capillary seal and the measurement module. The wash valve opens and a solid wash segment moves toward the sample port during this process.



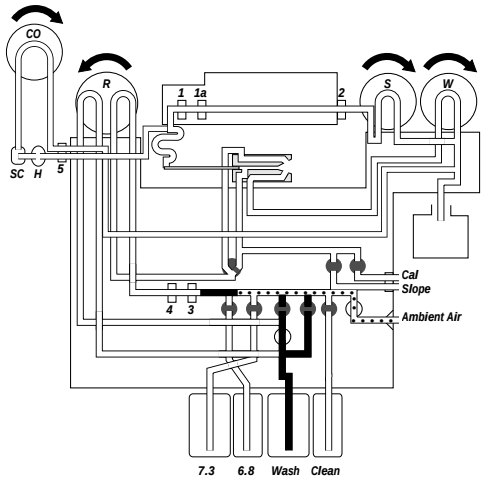
10. After the solid wash segment reaches the inner sample port, the reagent pump stops, the waste pump remains on, and the sample pump moves the wash segment from the sample port into the measurement module. An air segment follows. The wash valve opens and the reagent pump introduces another solid wash segment into the sample port. This sequence repeats 11 times to create wash segments that thoroughly clean the measurement module.



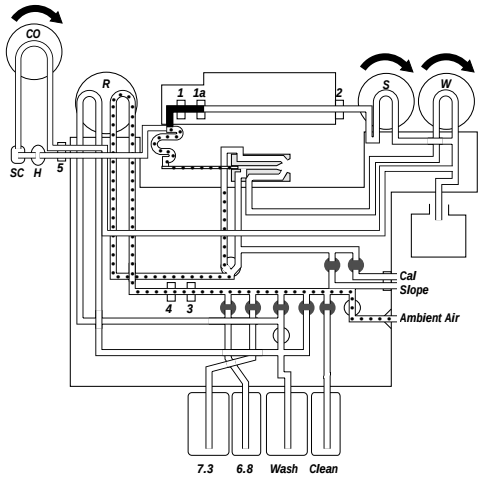
11. After the wash segments pass through the measurement module, the Cal gas valve opens and the sample pump starts to move Cal gas into the measurement module. The CO-ox module pump moves the remaining 7.3 reagent to the waste bottle. The waste pump is on to prevent a bubble from forming at the sample port. The sample door opens when the sequence completes.

Two-Point Calibration Sequence

The following steps describe the activities that take place during a two-point calibration.

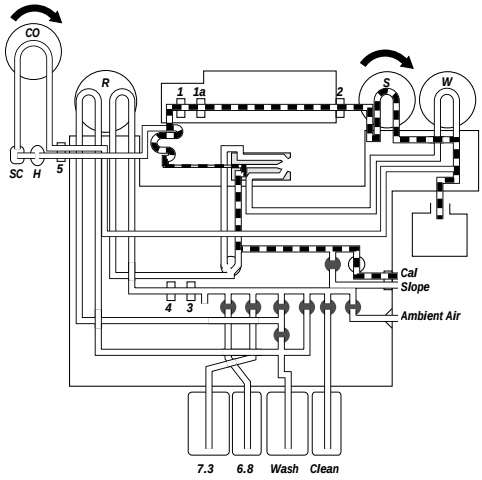


1. The sample door closes and the probe fully retracts. The reagent pump starts, the wash valve opens, and a wash segment is introduced into the reagent manifold. The sample and waste pumps start. The wash valve closes. The vent valve opens.

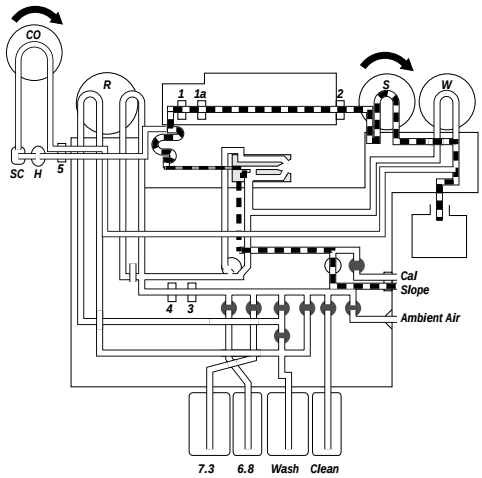


2. The vent valve, wash bypass valve, and diverter valve open. The sample pump and waste pump start. The wash segment moves through the measurement module to wet the sample path and allow humidification of the gas sensors.

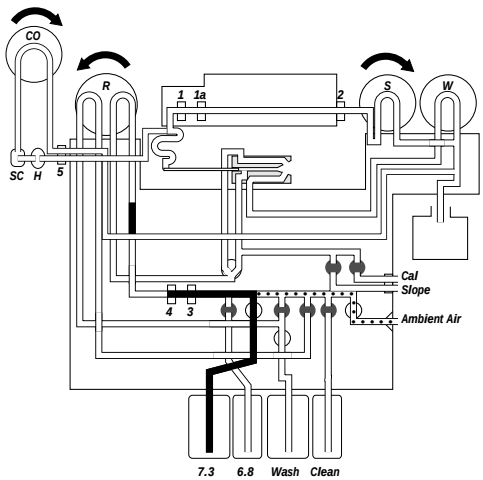
(Continued)



3. After the wash segment moves through the measurement module, the Cal gas and diverter valves open and Cal gas flows into the inner sample port. The sample pump aspirates the Cal gas at a controlled rate through the measurement module where pO_2 and pCO_2 are measured.

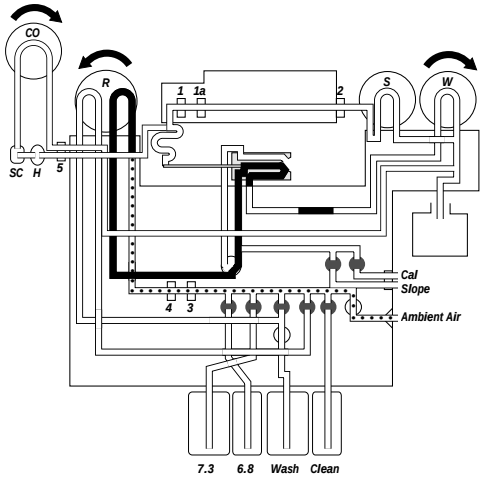


4. The Slope gas valve opens and Slope gas flows into the inner sample port. The sample pump aspirates the Slope gas at a controlled rate through the measurement module where pO_2 and pCO_2 are measured. The CO-ox pumps starts to prevent contamination of the sample connector by ambient air.

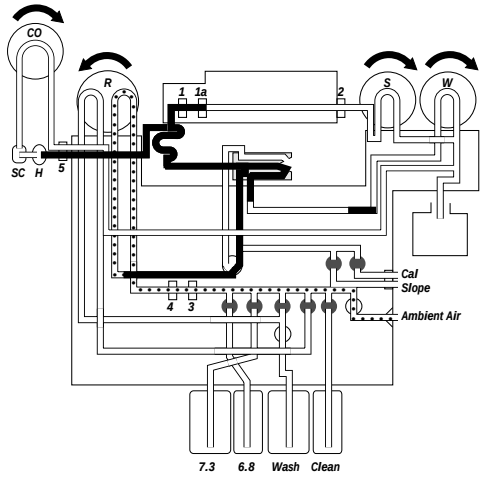


5. After the gases are measured, the 7.3 valve, wash bypass valve, and diverter valve open. The reagent pump moves a 7.3 reagent pre-segment and main segment from the reagent manifold toward the inner sample port. The sample pump is on.

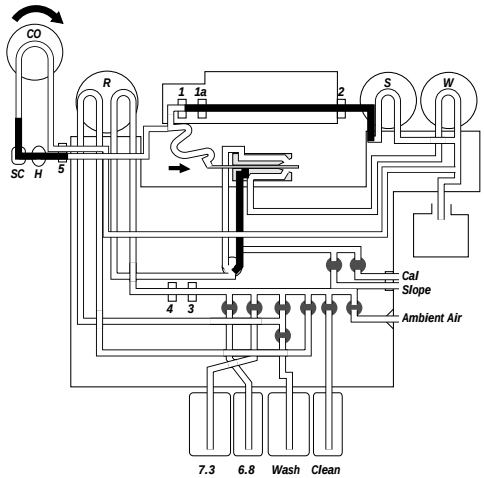
(Continued)



6. The reagent and sample pumps remain on. The pre-segment moves through the sample port into the waste and removes any residual reagent in the manifold.

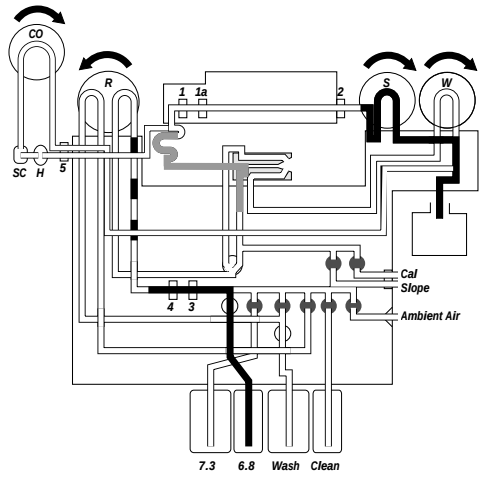


7. The main segment moves toward the sample port. When the main segment reaches the sample port, the sample pump starts and moves the segment to the measurement module until it is detected by fluid detector 1 and 1A.The CO-ox module pump moves the 7.3 reagent to FD5. The waste pump starts.

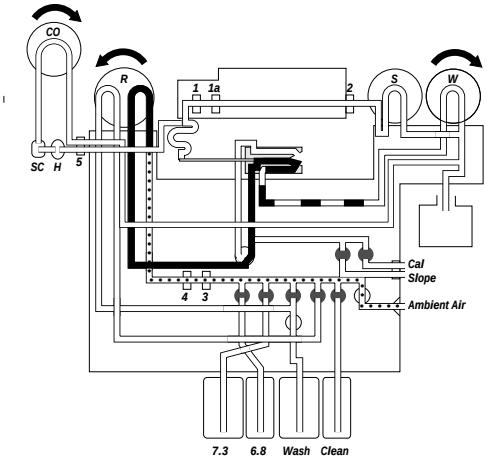


8. The probe extends and the main segment moves until the trailing edge is at fluid detector 1. The pumps stop and the analytes are measured. The CO-ox zero calibration is performed.

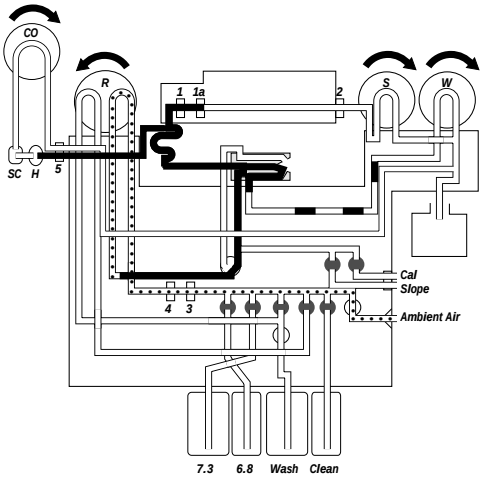
(Continued)



9. A small amount of foam wash is moved to the measurement module to remove the 7.3 reagent. The reagent pump then moves three 6.8 reagent pre-segments and a main segment to the inner sample port. The pre-segments are used to remove any residual 7.3 reagent from the pathways.

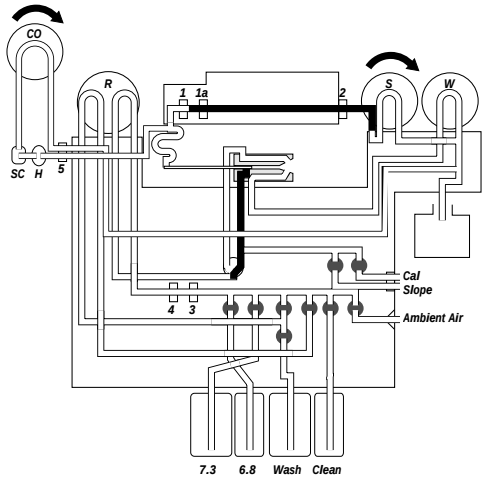


10. The pre-segments move through the sample port into the waste.

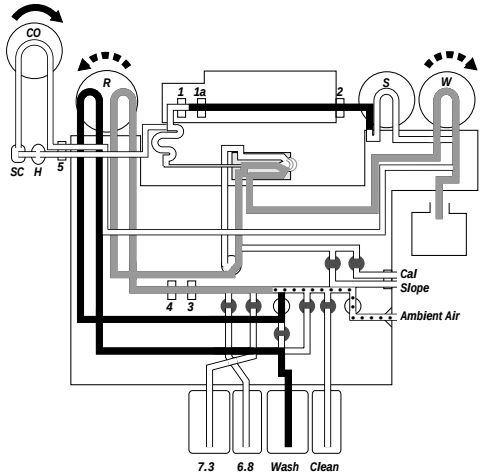


11. When the main segment reaches the sample port, the sample pump starts and moves the segment to the measurement module until it is detected by fluid detector 1 and 1A. The main segment moves toward the sample port. The waste pump starts.

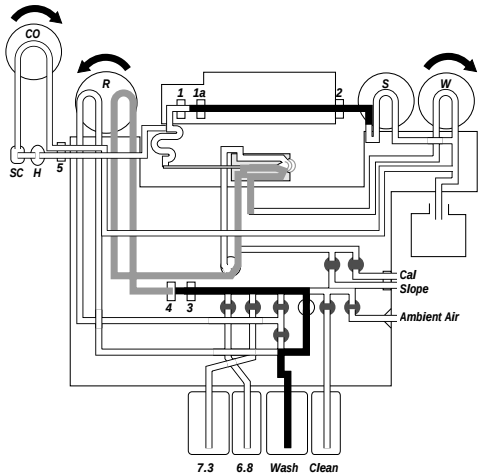
(Continued)



12. The probe extends and the main segment moves until the trailing edge is at fluid detector 1. The pumps stop and the analytes are measured.

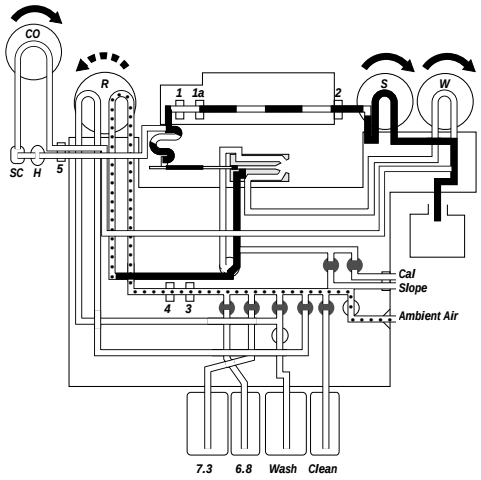


13. The sample port and reagent manifold are washed while the measurement is being made. The probe fully retracts. The foam wash and vent valves open, allowing the wash solution to become segmented with air, creating foam wash. The reagent pump starts and moves foam wash to the inner sample port. The reagent pump stops, the waste pump starts, and the foam wash is emptied from the sample port. This sequence repeats four times and is followed by a solid wash segment.

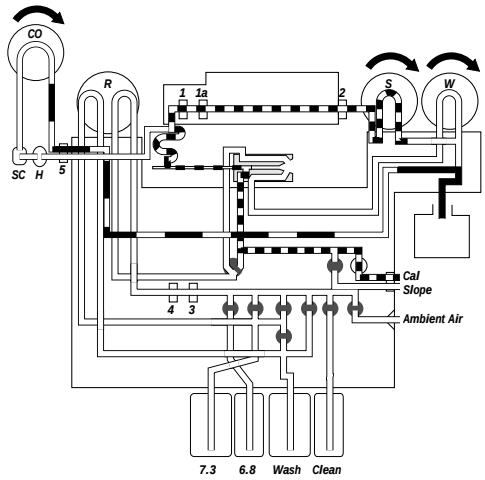


14. When the measurement completes, the reagent pump starts and moves the remaining foam wash to the inner sample port. The reagent pump stops, the waste pump starts, and the wash moves from the sample port to the waste. This cleans the inside of the capillary seal and the measurement module. The wash valve opens and a solid wash segment moves toward the sample port during this process.

(Continued)



15. After the solid wash segment reaches the inner sample port, the reagent pump stops, the waste pump remains on, and the sample pump moves the wash segment from the sample port into the measurement module. An air segment follows. The wash valve opens and the reagent pump introduces another solid wash segment into the sample port. This sequence repeats 11 times to create wash segments that thoroughly clean the measurement module.



16. After the wash segments pass through the measurement module, the Cal gas valve opens and the sample pump starts to move Cal gas into the measurement module. The waste pump is on to prevent a bubble from forming at the sample port. The sample door opens when the sequence completes.

2 Operating the System

Page

Overview of Sample Analysis

The 800 system indicates that it is ready to analyze samples when the following conditions exist:

- Ready screen appears
- sample door is open
- Analyze key is lit

  Do not attempt to analyze samples if the system is not ready.

The system aspirates all samples except expired gas samples. Aspiration reduces exposure to biohazardous materials and increases precision:

- by sampling the correct volume for each analysis
- by ensuring precise sample heating before sample analysis
- by reducing instrument-to-instrument and operator-to-operator variability

Identifying the Sample Device

The system automatically identifies the sampling device. If the system cannot identify the device, a message box appears prompting you to select one of the following sample devices:

- 1 mL syringe
- >2 mL syringe
- capillary

  Select the device type and press Enter. Then press Analyze to begin analysis.

Detecting Bubbles

If the system detects bubbles when it aspirates a sample, the Bubbles Detected in Sample message box appears. If the sample is not at point A or beyond, position the sample manually to continue with analysis.

Press . . .	*To . . .*
Sample in Place	begin analysis after you move the sample to the measurement module.
Cancel	cancel analysis. The system starts a wash and returns to the Ready screen.

If the system detects bubbles when the sample is in the measurement module, the Bubbles Detected in Sample message box appears. Look at the sample in the measurement module to see where the bubble is located because bubbles may affect the results of all the measured parameters.

Press . . .	*To . . .*
Report Results	continue with analysis. The report prints with the message, Bubbles Detected in Sample.
Cancel	stop analysis. The system starts a wash and returns to the Ready screen.

Accepting LIS Assay Orders

An LIS can send an order to perform a patient sample or QC sample analysis. If your system is connected to a laboratory or hospital information system or a data management system, you may see a message box prompting you to begin a patient sample assay.

The information system can also send a disable sampling order to the 800 system. A disabled sampling order appears in a message box when the 800 system is in the Analyze mode.

If you want to . . .	*Then . . .*
perform the assay	follow the instructions in the message box.
cancel the order	press **Cancel**.

Sending Results

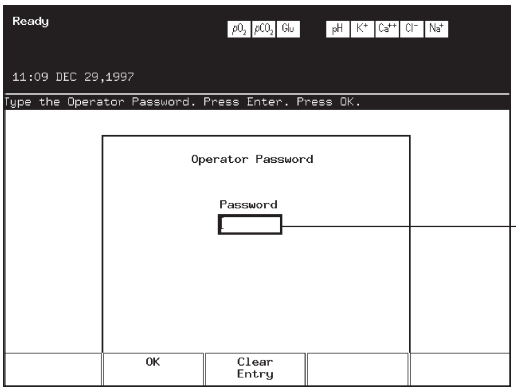
If your system is connected to a laboratory or hospital information system or a data management system and Auto Send is on, patient sample and QC sample results are automatically sent to the external system. If Auto Send is off, you can perform one of the following tasks when patient or QC analysis is complete:

Press . . .	*To . . .*
Send	transmit results.
Do Not Send	prevent transmission of results.

Entering Passwords

You may have to type a password before you can analyze samples and access certain menus. If your system requires a password, a prompt appears, as shown in Figure 2-1.

Figure 2-1. Entering an Operator Password



Password keystrokes do not appear on the screen.

1. Type your password in the password field.
2. Press **Enter** and then press **OK**.

   If you type the password incorrectly, a message box appears. Press **OK** and type the password again.

Procedural Notes

If your system requires a password to access selected menu options, the system prompts you to enter the Menu Options password.

Determining the Estimated Shunt Value

Arterial samples analyzed for blood gas and CO-oximeter values can determine the estimated shunt [Qsp/Qt (est,T)] value. To do this, turn the parameter on in Setup; refer to *Selecting Parameters for Analysis* in Section 5. Then during sample analysis, enter the F_IO_2 value. When arterial and mixed venous samples are combined for a-v studies, the estimated shunt value is replaced with the actual shunt value [Qsp/Qt (T)].

Analyzing Syringe Samples

The following tables list the minimum volumes required by each system to analyze syringe samples:

Table 2-1. Minimum Sample Volumes

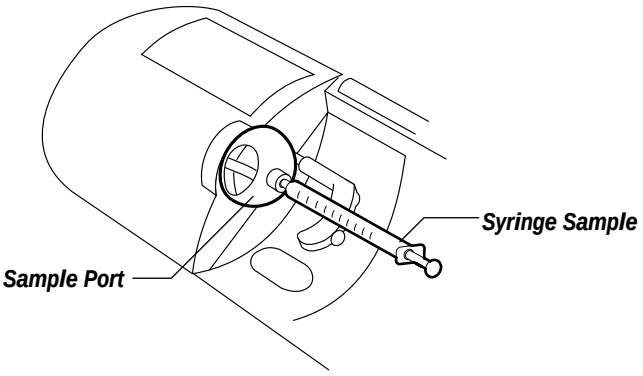
System	Minimum Sample Volume
840	90 µL
844, 845	140 µL
850	110 µL
854, 855	160 µL
860	125 µL
864, 865	175 µL

The system automatically aspirates the sample. If you want the system to analyze a different set of parameters for the sample, press Change Parameters to select another panel. Refer to *Selecting Parameter Panels*, page 2-29, for more information.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

1. Prepare the sample and insert the syringe into the sample port, as shown in Figure 2-2.

Figure 2-2. Inserting a Syringe Sample



CAUTION: To ensure the accuracy of the CO-ox measurement, close the CO-ox cover before pressing Analyze.

2. Press **Analyze**.

   The system aspirates the sample.

3. When prompted, remove the sample device.

4. Type the required information in the Patient Information screen and then press **Done**.

   NOTE: You can scan the patient ID and the accession number fields if your system uses the bar code option feature.

   Results appear on the screen and are continuously updated until analysis is complete. The system then displays the final results and prints the report.

   Refer to *Entering Patient Sample Data*, page 2-27 if you need more information to complete this screen.

5. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system continues to display the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

If the system determines that there is insufficient sample for routine analysis, a message appears prompting you to position the sample manually. Refer to *Analyzing Microsamples*, page 2-11, if you require additional information to move the sample manually.

To interrupt sample analysis at any time, press Cancel. The system stops analysis and performs a wash. The Ready screen appears when the wash finishes.

If you do not remove the syringe within 5 minutes of the screen prompt, the system completes analysis and performs a wash. When you remove the syringe, the Patient Information screen appears. Complete the screen as required.

Analyzing Capillary Tube Samples

The following table lists the minimum volumes required by each system to analyze capillary tube samples:

Table 2-2. Minimum Sample Volumes

System	Minimum Sample Volume
840	90 µL
844, 845	140 µL
850	110 µL
854, 855	160 µL
860	125 µL
864, 865	175 µL

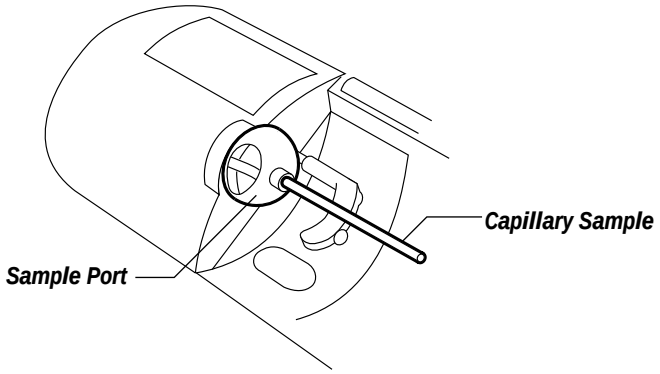
NOTE: If an 844, 845, 854, 855, 864, or 865 detects insufficient sample in the measurement module, the system analyzes the sample as a microsample. If you want the system to analyze a different set of parameters for the sample, press Change Parameters to select another panel. Refer to *Selecting Parameter Panels*, page 2-29, for more information.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

CAUTION: Insert the fire-polished end of the capillary tube into the sample port to prevent damage to the capillary seal.

1. Prepare the sample and insert the fire-polished end of the capillary tube into the sample port, as shown in Figure 2-3.

Figure 2-3. Inserting a Capillary Tube

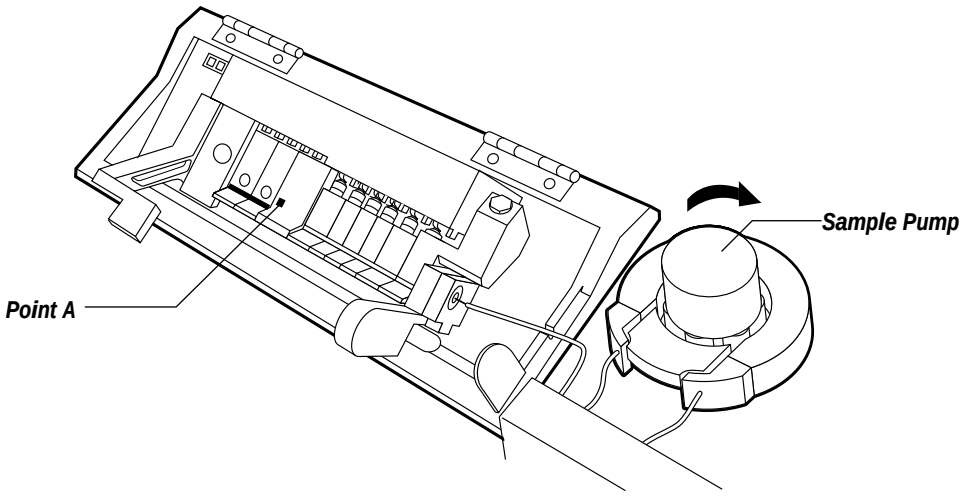


CAUTION: To ensure the accuracy of the CO-ox measurement, close the CO-ox cover before pressing Analyze.

2. Press **Analyze**.

If . . .	*Then . . .*
there is sufficient sample volume	the system automatically aspirates the sample and moves it to the measurement module.
the system prompts you to move the sample	a. Look to see if the sample has reached point A. If not, turn the sample pump clockwise to move the leading edge of the sample to point A, as shown in Figure 2-4. b. Press **Sample in Place**.

Figure 2-4. Sample at Point A on an 850



3. When prompted, remove the sample device.
4. Type the required information in the Patient Information screen and then press **Done**.
5. Perform the appropriate task.

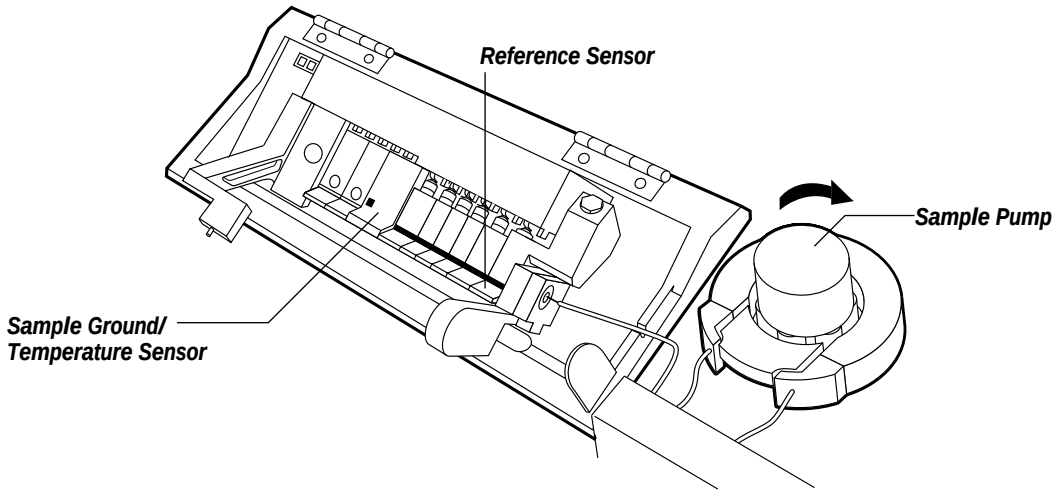
If . . .	*Then . . .*
the system is moving the sample	the results appear on the screen and are updated until analysis is complete. Continue with step 8.
you are moving the sample	continue with step 6.

850 860 **CAUTION:** Do not move the sample backward after it touches the reference sensor. The potassium and chloride values will be affected.

6. When prompted, turn the sample pump clockwise until the leading edge of the sample fills the reference sensor, as shown in Figure 2-5.

   NOTE: Ensure that the trailing edge of the sample remains in contact with the sample ground/temperature sensor.

Figure 2-5. Sample at the Reference Sensor on an 850



7. Press **Sample in Place**.

   Results appear on the screen and are continuously updated until analysis is complete. The system then displays the final results and prints the report.

8. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system continues to display the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

If the system analyzes an insufficient sample, the message, Insufficient Sample, prints on the roll printer report.

The system performs a wash and discards any data for the sample if any of the following occur:

- You press Cancel at any time to interrupt sample analysis.
- You do not remove a capillary tube within 5 minutes of the screen prompt.

Analyzing Microsamples

Use this procedure to analyze samples when the sample volume is too small for routine analysis. The system determines when a sample volume is too small for routine syringe or capillary analysis and prompts you to move the sample manually. The following table lists the minimum volumes required by each system to analyze a sample:

Table 2-3. Minimum Sample Volumes

System	Minimum Sample Volume
840, 844, 845	55 µL
850, 854, 855	70 µL
860, 864, 865	95 µL

When you use the Micro Sample option, you move the sample by manually turning the sample pump. The system analyzes the sample in two stages. First, the system analyzes pCO_2 and pO_2, then it analyzes the remaining parameters after you move the sample into position. Refer to *Selecting Parameter Panels*, page 2-29, for more information.

NOTE: The tHb parameters are not measured when you use the Micro Sample option on an 844, 845, 854, 855, 864, or 865.

If you want the system to analyze a different set of parameters for the sample, press Change Parameters to select another panel.

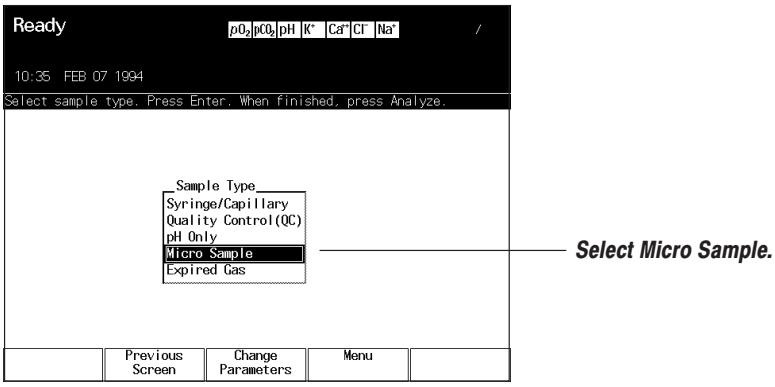
BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

CAUTION: When using capillary tubes, insert the fire-polished end of the capillary tube into the sample port to prevent damage to the capillary seal.

1. Prepare the sample and insert the device into the sample port.
2. Press **Change Sample Type**.

   The Sample Type menu appears, as shown in Figure 2-6.

Figure 2-6. Sample Type Menu



3. Select **Micro Sample** and press **Enter**.

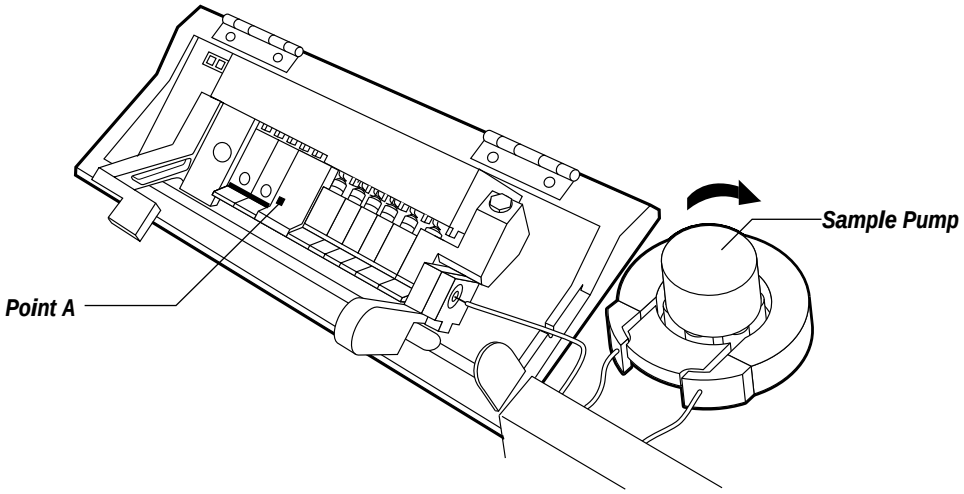
   NOTE: If the sample device is a syringe, the system tries to move the sample automatically for routine analysis. If the syringe contains sufficient volume, the system analyzes the sample automatically.

4. Press **Analyze**.

   The Position Sample Manually message box appears.

5. Turn the sample pump clockwise to move the leading edge of the sample to point A, as shown in Figure 2-7.

Figure 2-7. Sample at Point A on an 850



6. Press **Sample in Place**.
7. When prompted, remove the sample device.

8. Type the required information in the Patient Information screen and press **Done** when you finish.

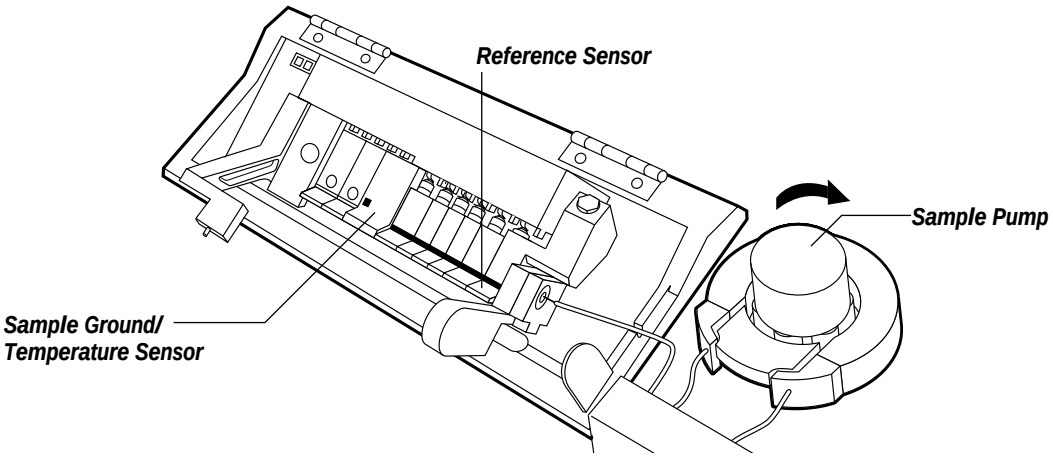
   Refer to *Entering Patient Sample Data*, page 2-27, if you need more information to complete this screen.

850 860 **CAUTION:** Do not move the sample backward after it touches the reference sensor. The potassium and chloride values will be affected.

9. When prompted, turn the sample pump until the leading edge of the sample fills the reference sensor, as shown in Figure 2-8.

   NOTE: Ensure that the trailing edge of the sample remains in contact with the sample ground/temperature sensor.

Figure 2-8. Sample at the Reference Sensor on an 850



10. Press **Sample in Place**.

    Results appear on the screen and are continuously updated until analysis is complete. The system then displays the final results and prints the report.

11. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system continues to display the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

If the system analyzes an insufficient sample, the message, Insufficient Sample, prints on the roll printer report.

The system performs a wash and discards any data for the sample if any of the following occur:

- You press Cancel at any time to interrupt a sample analysis.
- You do not press Sample in Place within 5 minutes of the screen prompt.
- You do not remove the capillary tube within 5 minutes of the screen prompt.

Analyzing CO-ox Only Samples

Use this procedure to determine the total hemoglobin content and available hemoglobin derivatives for a sample on an 844, 845, 854, 855, 864, and 865 systems. You can analyze syringe or capillary samples. The minimum sample volume requirement is 100 µL. If the system detects an insufficient volume, the analysis cannot be performed.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

1. Press **Change Parameters**.
2. Select **CO-ox** and press **Enter**.
3. Prepare the sample and insert the device into the sample port.

CAUTION: To ensure the accuracy of the CO-ox measurement, close the CO-ox cover before pressing Analyze.

4. Press **Analyze**.
5. When prompted, remove the sample device.
6. Type the required information in the Patient Information screen and then press **Done**.

   Refer to *Entering Patient Sample Data*, page 2-27, if you need more information to complete this screen.

   The system displays only the final results and prints the report.
7. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system continues to display the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

To interrupt sample analysis at any time, press Cancel. The system stops analysis and performs a wash. The Ready screen appears when the wash finishes.

If you do not remove the sample device within 5 minutes of the screen prompt, the system completes analysis and performs a wash. When you remove the sample device, the Patient Information screen appears. Complete the screen as required.

Analyzing pH Only Samples

Since pH samples are frequently capillary tubes with insufficient sample volume, the system requires you to move the sample manually to the measurement module. If the sample device is a syringe that contains sufficient volume for analysis, the system positions the sample automatically. The following table lists the minimum sample volumes required by each system to determine pH:

Table 2-4. Minimum Sample Volumes

System	*Minimum Sample Volume*
840, 844, 845	35 µL
850, 854, 855	70 µL
860, 864, 865	95 µL

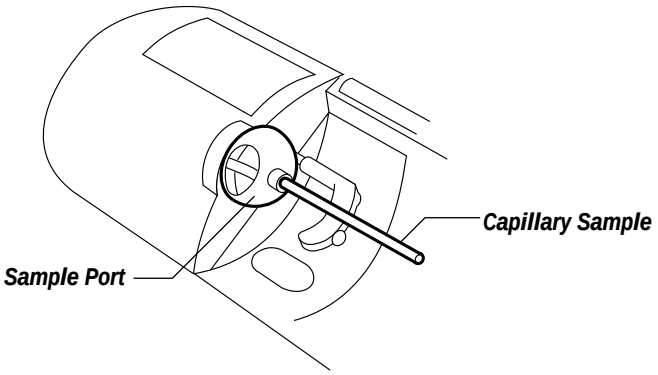
850 860 **NOTE:** When you select pH only, the system measures everything except pCO_2 and pO_2. On systems with the CO-ox module, the system measures everything except pCO_2, pO_2, and tHb parameters.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

CAUTION: Insert the fire-polished end of the capillary tube into the sample port to prevent damage to the capillary seal.

1. Prepare the sample and insert the device in the sample port. Figure 2-9 shows a capillary sample in the sample port.

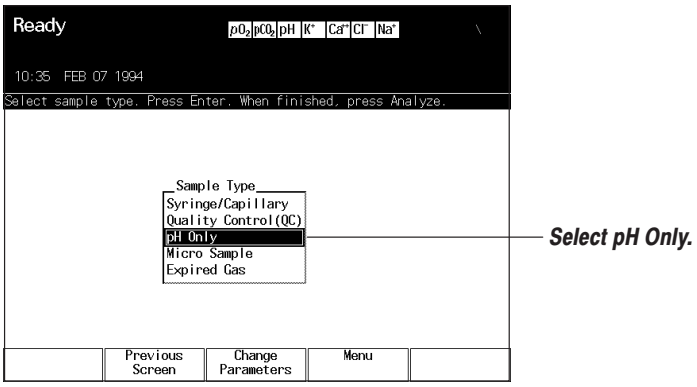
Figure 2-9. Inserting a Capillary Sample



2. Press **Change Sample Type**.

   The Sample Type menu appears, as shown in Figure 2-10.

Figure 2-10. Sample Type Menu

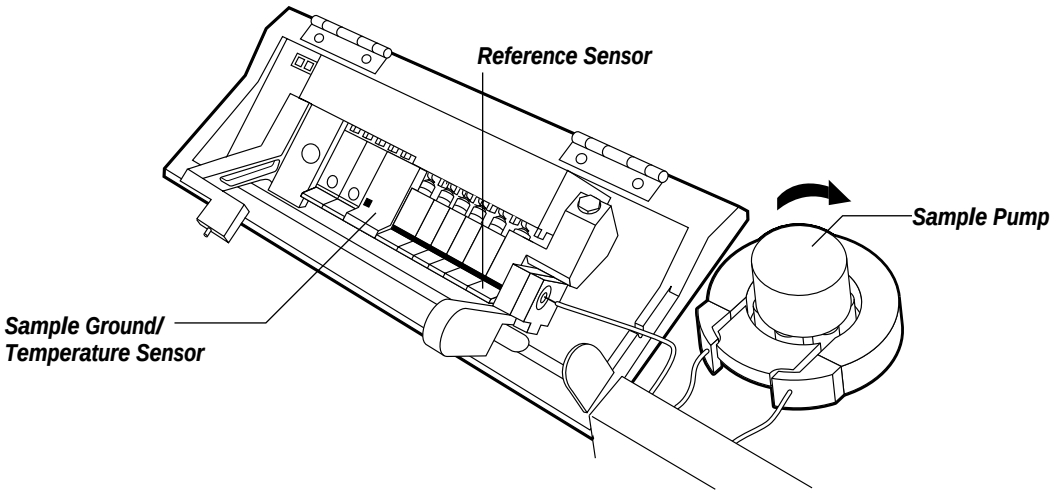


3. Select **pH Only** and press **Enter**.
4. Press **Analyze**.

   NOTE: Ensure that the trailing edge of the sample remains in contact with the sample ground/temperature sensor.

5. Turn the sample pump clockwise until the leading edge of the sample fills the reference sensor, as shown in Figure 2-11.

Figure 2-11. Sample at Reference Sensor on an 850



6. Press **Sample in Place**.

7. When prompted, remove the sample device.
8. Type the required information in the Patient Information screen and then press **Done**.

   Refer to *Entering Patient Sample Data*, page 2-27, if you need more information to complete this screen.

   Results appear on the screen and are continuously updated until analysis is complete. The system then displays the final results and prints the report.
9. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system continues to display the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

If the system analyzes an insufficient sample, the message, Insufficient Sample, prints on the roll printer report.

The system performs a wash and discards any data for the sample if any of the following occur:

- You press Cancel at any time to interrupt a sample analysis.
- You do not press Sample in Place within 5 minutes of the screen prompt.
- You do not remove the capillary tube within 5 minutes of the screen prompt.

Analyzing Vacuum Tube Samples

The following table lists the minimum volumes required by each system to analyze vacuum tube samples:

Table 2-5. Minimum Sample Volumes

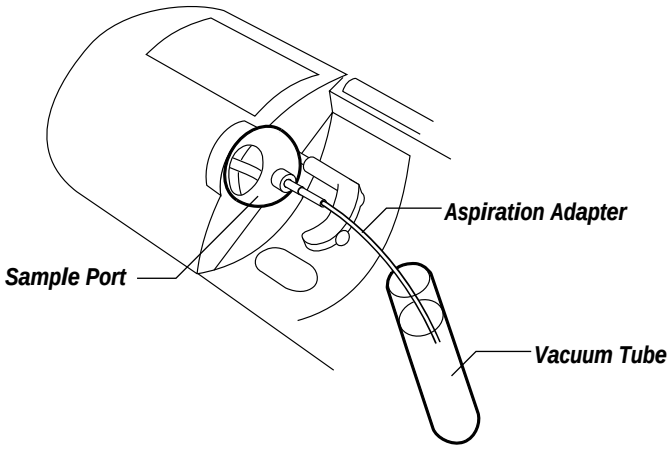
System	Minimum Sample Volume
840	90 µL
844, 845	140 µL
850	110 µL
854, 855	160 µL
860	125 µL
864, 865	175 µL

If you want the system to analyze a different set of parameters for the sample, press Change Parameters to select another panel. Refer to *Selecting Parameter Panels*, page 2-29, for more information.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

1. Prepare the sample and insert an aspiration adapter into the sample port.
2. Insert the adapter into the vacuum tube, as shown in Figure 2-12.

Figure 2-12. Inserting an Aspiration Adapter with a Vacuum Tube Sample



CAUTION: To ensure the accuracy of the CO-ox measurement, close the CO-ox cover before pressing Analyze.

3. Press **Analyze**.
4. When prompted, remove the aspiration adapter.
5. Type the required information in the Patient Information screen and then press **Done**.

   Refer to *Entering Patient Sample Data*, page 2-27, if you need more information to complete this form.

   Results appear on the screen and are continuously updated until analysis is complete. The system then displays the final results and prints the report.
6. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system continues to display the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

If the system determines that there is insufficient sample for routine analysis, the system prompts you to position the sample manually. Refer to *Analyzing Microsamples*, page 2-11, if you require additional information to move the sample manually.

To interrupt sample analysis at any time, press Cancel. The system stops analysis and performs a wash. The Ready screen appears when the wash finishes.

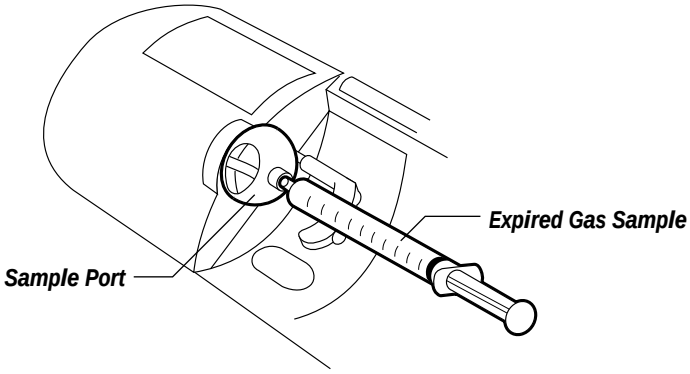
Analyzing Expired Gas Samples

Use this procedure to analyze expired gas samples. During this procedure, you inject the gas into the system. The minimum sample volume requirement is 10 mL.

BIOHAZARD: Refer to Appendix A , *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

1. Prepare the sample and insert the syringe in the sample port, as shown in Figure 2-13.

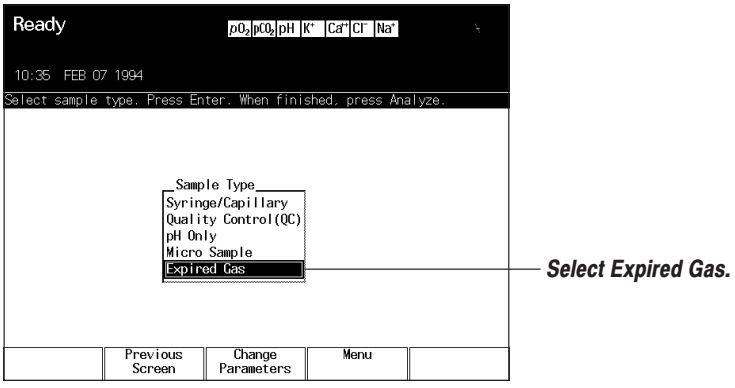
Figure 2-13. Inserting an Expired Gas Sample



2. Press **Change Sample Type**.

   The Sample Type menu appears, as shown in Figure 2-14.

Figure 2-14. Sample Type Menu



3. Select **Expired Gas** and press **Enter**.
4. Press **Analyze**.

   Wait for the sample pump to start.
5. When the pump starts, slowly inject gas until the sample pump stops. Inject at least 10 mL of gas.

6. When prompted, remove the sample device.
7. Type the required information in the Patient Information screen and then press **Done**.

   Refer to *Entering Patient Sample Data*, page 2-27, if you need more information to complete this screen.

   Results appear on the screen and are continuously updated until analysis is complete. The system then displays the final results and prints the report.
8. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system continues to display the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

To interrupt sample analysis at any time, press Cancel. The system stops analysis and performs a wash. The Ready screen appears when the wash finishes.

The Sample Source field on the Patient Information screen contains the words, Expired Gas. You cannot change this field.

Analyzing Samples to Combine with 270 CO-oximeter Results

Use this procedure to analyze a patient sample at an 840, 850, or 860 system and combine the results with results from a sample analyzed at a 270 CO-oximeter that is connected to one of these systems. Refer to Appendix D, *Connecting to External Devices*, for information about connecting the 270 CO-oximeter to an 800 base model.

To combine results, you must simultaneously analyze the sample at the 800 system and the 270 CO-oximeter. The 800 system assigns a sequence number to each sample and reports sample results by this number. The 800 system stores the 270 results and prints a report showing the blood gas, CO-oximeter, and combined results. The 800 also stores any pass-through results from the 270. You can recall these results from the 800 system. Refer to Appendix F, *Printed Reports*, to see an example of a combined report.

If you want the system to analyze a different set of parameters for the sample, press Change Parameters to select another panel. Refer to *Selecting Parameter Panels*, page 2-29, for more information.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

1. Prepare the sample and introduce the sample at the 270 CO-oximeter.
2. Insert the device into the sample port at the 840, 850, or 860 system.
3. Press **Analyze**.
4. When prompted, remove the sample device.
5. When prompted, remove the sample device.

CAUTION: If your laboratory requires you to enter an ID number at each system, be sure that you enter the same ID number at each system. The patient ID you enter at your 800 system and the sample ID you enter at your 270 CO-oximeter must match to combine results.

6. Return to the 800 system and type the required information in the Patient Information screen. Press **Done** when you finish.

   Refer to *Entering Patient Sample Data*, page 2-27, if you need more information to complete this screen.

7. If required by your laboratory, type the sample ID at your 270 CO-oximeter.

   When the CO-oximeter data is available, the 800 system displays the final results and prints the report.

8. Press **Home** to return to the Ready screen. If you do not press Home, the system automatically returns to the Ready screen after 45 seconds.

Procedural Notes

If the patient ID entered at the 800 system and the 270 CO-oximeter do not match, the Patient ID Mismatch message box appears.

If . . .	*Then . . .*
you want to combine the 270 results with the 800 system results	a. Press **Combine Results**. The Patient Information screen appears. b. Type the patient ID and press **Done**.
you do not want to combine the 270 results with the 800 system results	press **Cancel**. Separate reports are generated at the 270 CO-oximeter and at the 800 system.

If the 800 system completes analysis before the 270 CO-oximeter completes analysis, the Waiting for CO-oximetry Results message box appears.

If . . .	*Then . . .*
you want to combine results	press **Combine Results**. The 800 system creates a combined report when the results are ready.
you do not want to combine results	press **Cancel**. Separate reports will be generated at the 270 CO-oximeter and at the 800 system.

Analyzing Samples for a-v Studies

Use this procedure to combine an arterial blood sample with a venous or mixed venous blood samples to create an a-v studies report.

Sample Requirements

To complete a-v studies successfully, ensure that the samples meet the following requirements:

- The difference between analysis times of the two samples at the 800 system must be less than 60 minutes.
- Each sample can have the same draw date and draw time, no draw date or draw time, or only one sample with a draw date and draw time.
- Each sample must have the same patient ID.
- Samples must be analyzed on the 800 for blood gas and CO-oximeter values.
- You cannot combine results using a sample that was already combined with another sample. For example, you cannot combine one arterial sample with two different venous samples.

Sample Results

Samples analyzed for a-v studies can produce the following results:

- *c*tO_2(a-v)
- *c*tO_2([a-v]/a)
- VO_2
- DO_2
- Qsp/Qt(T)

The system determines a-v study results using the following rules:

- VO_2 and DO_2 results are determined only if the cardiac output value (Qt) is entered during the a-v studies procedure. The Qt value cannot be entered after the a-v study results are complete.
- Qsp/Qt(T) value is determined only when arterial and mixed venous are selected for a-v studies. Any estimated shunt value that appeared on the arterial report is removed after the a-v study results are complete.
- The *c*tO_2(a) value is added to the venous results, and the *c*tO_2(v) value is added to the arterial results.

NOTE: When analyzing patient samples that will be used for a-v studies, be sure to select arterial as the sample source for one sample and either venous or mixed venous as the sample source for the other sample.

1. Analyze the arterial, and the venous or mixed venous samples you want to use for a-v studies.
2. Select the first patient sample for a-v studies:

   a. Select **Menu**.

   b. Select **4 Data Recall** and press **Enter**.

   c. Select **1 Patient Data** and press **Enter**.

   The Patient Data Search Criteria screen appears.
3. Enter the patient ID for the sample and press **Done**.

   The Patient Data Search Log screen appears.
4. Select the patient sample for a-v studies and press **Reporting Options**.

   The Reporting Options message box appears.
5. Select **Select for a-v Studies** and press **OK**.

   The First a-v Sample Selected message box appears.
6. Press **OK**.

If . . .	***Then . . .***
only one sample is found	the Patient Data Search Result screen appears. Press **Reporting Options**. The Reporting Options message box appears.
more than one sample is found	the Patient Data Search Log screen appears. a. Select the next sample for a-v studies and press **Enter**. b. Press **Reporting Options**. The Reporting Options message box appears.

7. Select **Select for a-v Studies** and press **OK**.

   The Confirm Samples for a-v Studies message box appears.

   NOTE: Record and use the sequence numbers to access the sample results from the Patient Data Search Log.
8. Enter the Qt value if you want VO_2 and DO_2 results.

9. Press **OK** to create the a-v study results.
   The Patient Data Search Log screen appears.
10. Select the sample used for a-v studies and press **Enter**.
    The Patient Data Search Result screen appears.
11. Press **Next Screen** to view the a-v study results.

Procedural Notes

The a-v results are not automatically sent to the LIS. Select Reporting Options on the patient results screen, and then select Send Results to transmit the results to an LIS.

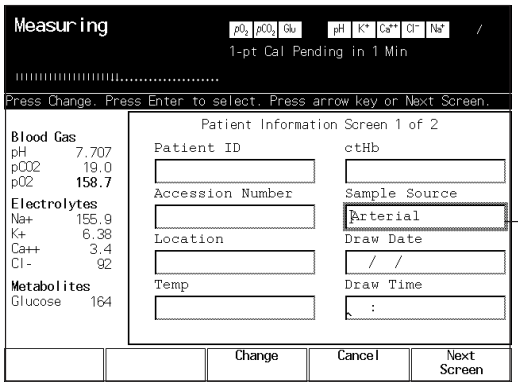
If the Invalid Selection message box appears, review the sample requirements to ensure that the samples selected meet the requirements. Then select the samples again.

Entering Patient Sample Data

Use this procedure to enter data in the Patient Information screen. The Patient Information screen appears on the screen during sample analysis after you remove the sample device. Figure 2-15 shows the default Patient Information screen.

NOTE: The Patient Information screen may appear differently on your system. Certain fields may not appear because they were turned off. Depending on the number of data entry fields defined for your system, you may have only one patient information screen. The Sample Source field has the default value of arterial.

Figure 2-15. Patient Information Screen



When the cursor is at Sample Source, press Change to select a sample source.

NOTE: Any field that has a ▶ symbol is a required field and must be completed.

1. Type the patient ID and press **Enter**. You can enter patient sample data using the keypad, an optional keyboard, or a bar code scanner.

   NOTE: When scanning a bar code label, the correct field must be highlighted. If a field other than the Patient ID or Accession Number is highlighted as you scan a label, the field remains blank and no data is entered. Refer to the *800 Series Bar Coding Features* technical bulletin for detailed information about using the bar code option.

2. Enter data in the remaining fields until all required fields are completed. Press the arrow keys to move to other fields.

3. Press **Next Screen**.

   The second Patient Information screen appears.

4. Enter data in all required fields.
5. Press **Done**.

   The Patient Information screen closes.

If you want to make changes to the Patient Information screen during analysis, press **Edit Patient Data**. The Patient Information screen reappears. Make your changes to the fields and press **Done**.

Procedural Notes

If you do not complete all required fields before you press Done, a message box appears prompting you to complete the required data entry fields. Press **OK** to return to the Patient Information screen. The incomplete field is highlighted.

If you do not complete data entry within 5 minutes, the system stores the sample result, and enters a message containing a sequence number, the date, and the time of analysis in the status log. The system returns to the Ready screen. You can search for the sample results by sequence number and analysis time, and then enter the patient data for the sample. Refer to *Recalling Patient Sample Data*, page 2-35.

Procedural Notes

You can enter a patient's year of birth in a 2-digit or 4-digit format. However, the system stores, prints, and transmits the birth year in a 4-digit format.

If you enter the birth year in a 2-digit format (xx), the system assumes the birth year to be 19xx.

In the year 2000 and beyond, you must enter birth years in the 4-digit format to ensure an accurate birthdate and patient age. The system verifies that the 4-digit year entered is the current or a prior year. The valid range for years entered as 4 digits is 1880 to 2050.

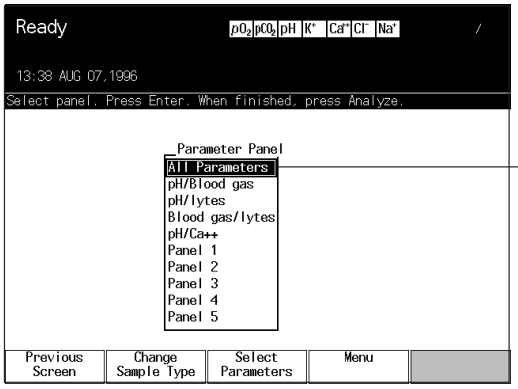
Selecting Parameter Panels

Use this procedure when you want to measure specific parameters for a single patient sample. After the sample is analyzed, the system restores the default panel for your system. Different panels are available for each system.

1. Press **Change Parameters**.

   The Parameter Panels menu appears, as shown in Figure 2-16.

Figure 2-16. Parameter Panels Menu for an 850 System



2. Select a parameter.

If you want to select . . .	*Then . . .*
one of the panels displayed	select the parameter panel and press **Enter**. Custom panels are listed as Panels 1–5 and are defined during system setup by the system administrator or authorized personnel.
specific parameters to analyze	a. Press **Select Parameters**. The Select Parameters screen appears. b. Select the parameters you want and press **Done** to return to the Ready screen.

3. Insert the sample device into the sample port.
4. Press **Analyze**.

Procedural Notes

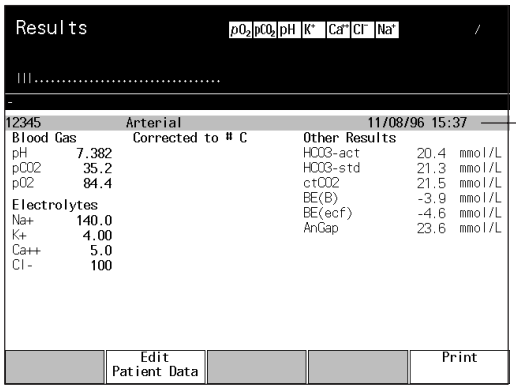
After the next sample is analyzed, the default panel is restored.

If you select Previous Screen, the system returns to the Ready screen and restores the default panel.

About Patient Sample Results

This section provides an overview of the Patient Sample Results screen and the printed sample report. Figure 2-17 shows the results screen. Your screen may appear differently depending on your system and how parameters were defined in setup.

Figure 2-17. Patient Sample Results Screen for an 850 System



The following table describes the symbols seen in patient sample reports:

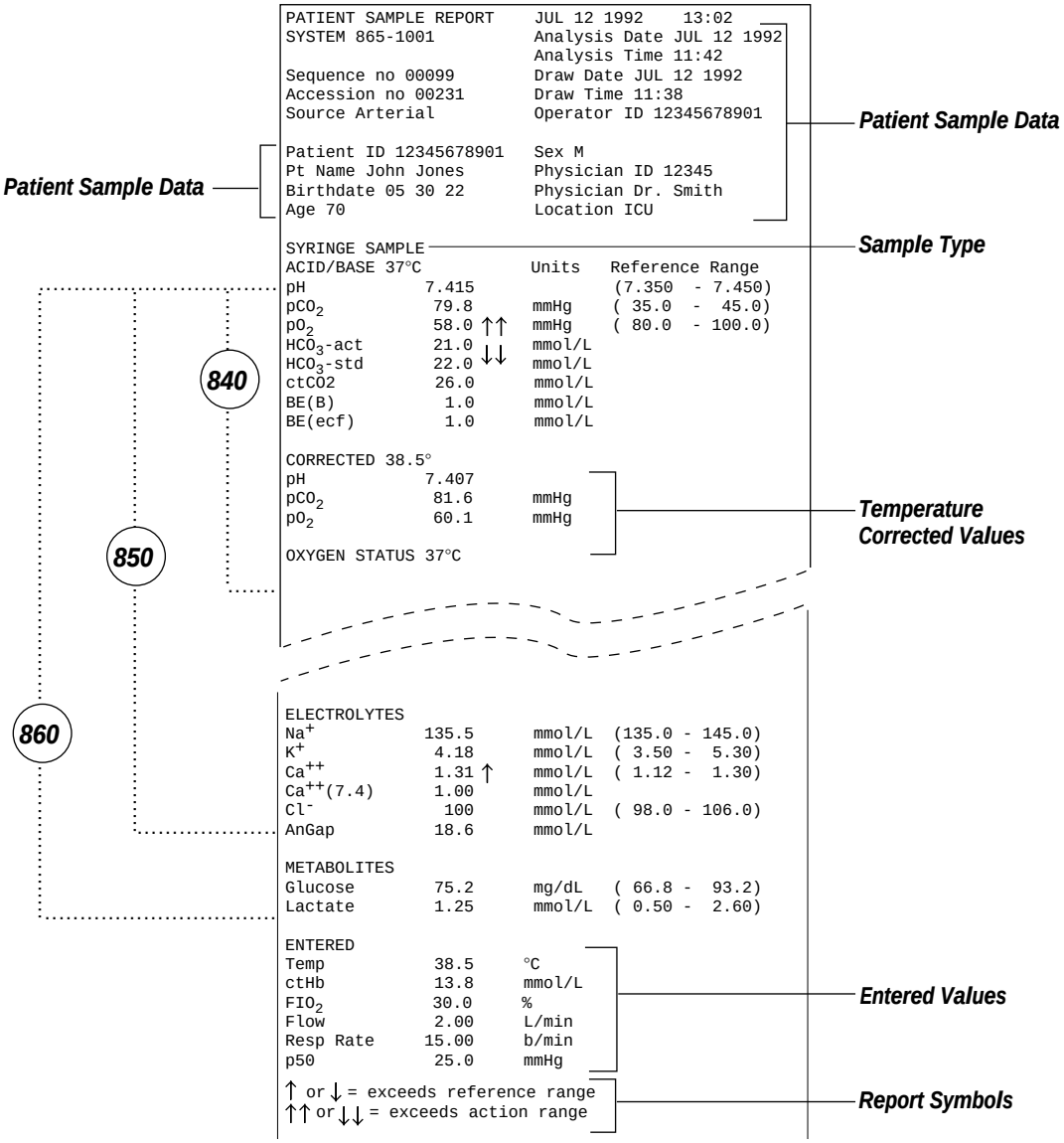
Symbol	*Description*
******	The sensor is out of calibration.
------↑	The result is above the measurement range. On the screen, the result, dashes, and arrow appear in red.
------↓	The result is below the measurement range. On the screen, the result, dashes, and arrow appear in red.
*	The patient sample did not reach endpoint.
↑	The patient sample result is above the reference range. On the screen, the result and arrow appear in red.
↓	The patient sample result is below the reference range. On the screen, the result and arrow appear in red.
↑↑	The patient sample result is above the action range. On the screen, the result and arrow appear in red.
↓↓	The patient sample result is below the action range. On the screen, the result and arrow appear in red.

(Continued)

Symbol	Description
#	The patient sample contains substances that may interfere with glucose or lactate measurement.
?	Optical measurements indicate that the CO-oximeter results should be reviewed. See *Troubleshooting Patient Results* in Section 4.

Figure 2-18 shows an example of a printed report. Your printed report may appear differently depending on your system and how parameters were defined in setup.

Figure 2-18. Patient Sample Report



The following table describes the messages that may appear in patient sample reports on the roll printer:

Message	*Description*
****** = Not in Calibration	The sensor is out of calibration.
------↑ or ------↓ = Out of Range: ____	The result is above or below the measurement range.
* = D5 No Endpoint: __	The sensor did not reach a stable reading within the predefined time limit.
* = exception or D–code noted (in Patient Data Log)	The sample has an exception or D code. Appears in Patient Data Log.
↑ or ↓ = exceeds reference range	The result is above or below the reference range.
↑↑ or ↓↓ = exceeds action range	The result is above or below the action range.
? = If blood, question data	Optical measurements indicate that the CO-oximeter results should be reviewed. See *Troubleshooting Patient Results* in Section 4.
SulfHb > 1.5%	The system detects a sulfhemoglobin concentration greater than 1.5% in a CO-ox sample.
# = Interfering Substance: Glu	The system detects the presence of substances in the sample that may interfere with glucose measurement. **NOTE:** Repeated, unexpected occurrence of this message may indicate sensor failure. See *Troubleshooting Patient Results* in Section 4.
# = Interfering Substance: Lac	The system detects the presence of substances in the sample that may interfere with lactate measurement. **NOTE:** Repeated, unexpected occurrence of this message may indicate sensor failure. See *Troubleshooting Patient Results* in Section 4.
D38 Temperature Error	The system detects an error in the temperature control system of the base model.
Bubbles Detected In Sample	The system detects a non-continuous fluid in the sample path of the base model.

(Continued)

Message	Description
COox Cover Open During Meas	The cover on the CO-ox module was open while the system was analyzing the sample.
COox Sample Chamber Temp Error	The CO-ox module sample chamber temperature is ± 0.35°C of range and cannot accept sample analysis requests.
COox Sample Temp Out of Range	The CO-ox module sample chamber temperature is not in range at the end of a measurement sequence.
Edited Report	The Patient Information screen was edited after initial completion.
Excessive Bubbles in COox Sample	The CO-ox module detects a non-continuous fluid in the sample path.
D2 Excessive Drift: __	The sensor drift is beyond predefined limits during a one-point or a two-point calibration.
Data Entry Incomplete __ Not Sent	Appears when required data entry fields were not completed and Auto Send is turned on.
Insufficient COox Sample	Appears when there is not enough sample to fill the CO-ox module sample chamber and the analysis cannot be performed.
Insufficient Sample	Appears when there is not enough sample to fill the measurement module and you manually positioned the sample for measurement.
Interfering Substance Detected	Substances that interfere with analysis are present in the sample. Only appears when 270 CO-ox is attached.
Interfering Substance: tHb	The CO-ox module detects the presence of substances in the sample that may interfere with the measurement.
Measurement Module Temp Error	The measurement module temperature is not in range and the system cannot accept sample analysis requests.
Measurement Module Temp Warning	The measurement module temperature is ± 0.15°C of range and can accept sample analysis requests.
__ Not Sent	Appears when you press Do Not Send at the end of analysis.

(Continued)

Message	Description
Sample Temperature Out of Range	The measurement module temperature is not in range at the end of measurement sequence.
__ Sent	Appears when you press Send at the end of analysis.

Recalling Patient Sample Data

Use this procedure to recall patient sample data and results stored in the system. When the system locates patient sample data, you can edit data, print reports, and transmit the data to an LIS or a data management system.

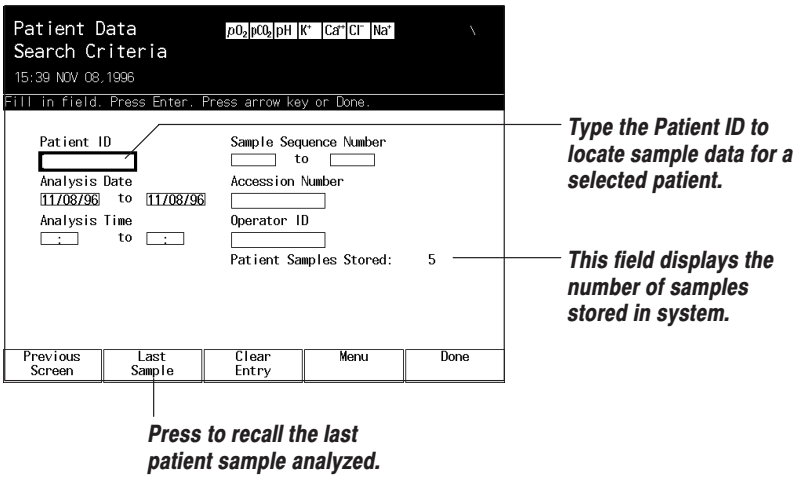
Menu Code

4 ***1***

1. Access the Patient Data Search Criteria screen from the Menu screen:
   a. Select **4 Data Recall** and press **Enter**.
   b. Select **1 Patient Data** and press **Enter**.

   The Patient Data Search Criteria screen appears, as shown in Figure 2-19.

Figure 2-19. Patient Data Search Criteria Screen



NOTE: The Analysis Date fields contain the current day's date. If you do not complete any other fields, the system recalls all patient samples for this day.

Use this screen to enter the criteria that you want the system to use to search for patient sample data. The system locates only the samples that meet all the criteria you specify. For example, if you enter a patient ID, the system searches for all samples with that patient ID. If you enter a patient ID and an analysis date, the system searches only for samples with that patient ID and analysis date. If you do not complete any of the criteria fields, the system recalls all the samples stored in the system.

2. Type the search criteria and press **Enter** after you complete each field.

To search . . .	*Then . . .*
for a selected date	type the date in both Analysis Date fields.
from the earliest date to the present date	leave the Analysis Date and Analysis Time fields blank.

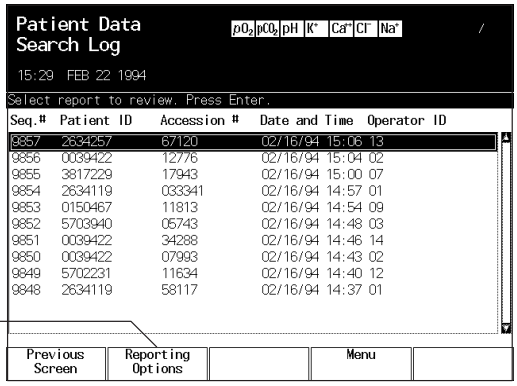
(Continued)

To search . . .	*Then . . .*
from the earliest date to a specific date	leave the Analysis Date From field blank, and type the specified date in the Analysis Date To field.
from a specific date to the present date	type the start date in the Analysis Date From field, and type nothing in the Analysis Date To field.
for a specific range of dates	type the start date in the Analysis Date From field, and type the end date in the Analysis Date To field.
by shift or any other specific time period	type the start time in the Analysis Time From field, and type the end time in the Analysis Time To field.
by sequence and accession number	type the sequence number in the first Sample Sequence Number field.

3. Press **Done**.

If . . .	*Then . . .*
more than one sample is found	the Patient Data Search Log screen appears, as shown in Figure 2-20. The log contains the reports that the system located for the search criteria specified. The most recent report appears first. Use the log to select reports you want to view, edit, print, or transmit. You can also print the log.
one sample is found	the Patient Data Search Result screen appears, as shown in Figure 2-21.

Figure 2-20. Patient Data Search Log Screen

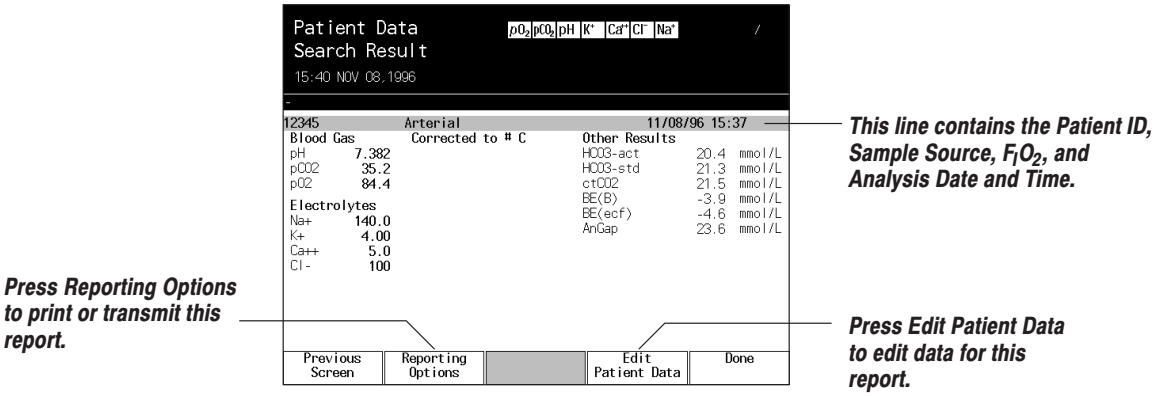


Press Reporting Options to print or transmit a report selected from the log.

4. Select the report that you want to view and press **Enter**.

   The Patient Data Search Result screen appears.

Figure 2-21. Patient Data Search Result Screen



5. Edit, print, or transmit the appropriate patient reports.
6. Press **Done** when you finish.

If . . .	*Then . . .*
more than one sample is found	the Done Options message box appears. • Select Next Record and press **OK** to view the next report that appears on the log. • Select Previous Record and press **OK** to view the previous report that appears on the log. • Select Search Criteria Screen and press **OK** to view the Patient Data Search Criteria screen. • Press **Cancel** to close this message box and return to the Search Results screen.
one sample is found	the Patient Data Search Criteria screen appears as shown in Figure 2-19.

Refer to the following procedures to edit patient data, print the report or the log, or transmit the report.

Procedural Notes

If you press Home while in the Patient Data Search Criteria screen, all data is cleared from the fields and the Ready screen appears.

If you want to recall patient samples for which no fields in the Patient Information screen were completed, use the sequence number or the date and time of analysis for the search criteria. View the Patient Data Search Log to locate the sequence number and date and time of analysis.

If the selected sample has a D code or status message associated with it, the View Diagnostics F-key appears. Press View Diagnostics to view the Diagnostics message box. Scroll through the D codes and messages. Press Cancel when you finish.

If no patient sample results are recalled, the system prompts you to ensure the accuracy of the search criteria or to enter new search criteria.

Editing Patient Sample Data

Use this procedure to edit patient information that you recall. You can edit patient information in the following ways:

- Change the sample temperature or the hemoglobin value and recalculate the results.
- Change the text in fields on the Patient Information screen. You cannot edit fields that are entered by the system, such as Analysis Date and Time and Sequence Number.

1. Use the procedure described in *Recalling Patient Sample Data,* page 2-35, to locate the sample you want to edit.
2. Press **Edit Patient Data**.

   The Patient Information screen appears.

If you want to . . .	*Then . . .*
enter a new temperature and recalculate results	a. Move to the temperature field. b. Press **Clear Entry**. c. Type the new temperature. d. Press **Enter.**
enter a new hemoglobin value and recalculate results	a. Move to the tHb field. b. Press **Clear Entry**. c. Type the new value. d. Press **Enter.**

3. Press **Done**.

   The system displays the Results screen, which now contains the changes you made.
4. Press **Home** to return to the Ready screen.

Procedural Notes

If you change the patient ID to match another existing patient ID, the Duplicate Patient ID message box appears.

Press . . .	To . . .
Continue	accept the patient ID and return to the Patient Information screen.
Cancel	return to the Patient Information screen without accepting the patient ID.

Printing or Transmitting Patient Sample Data

Use this procedure to print or transmit data from the Patient Data Search Log screen or the Patient Data Search Result screen.

1. Locate the sample you want as described in *Recalling Patient Sample Data*, page 2-35.
2. Press **Reporting Options**.

   The Reporting Options message box appears.

If you want to . . .	Then . . .
print a sample report	a. Select Print Report and press **Enter**. b. Press **OK**. Refer to Figure 2-18 for an example of a patient sample report.
transmit sample results to an LIS or HIS	a. Select Send Results and press **Enter**. b. Press **OK**.

3. Press **Home** to return to the Ready screen.

Procedural Notes

If the selected sample has a D code or status message associated with it, the View Diagnostics F-key appears. Press View Diagnostics to view the Diagnostics message box. Scroll through the D codes and messages. Press Cancel when you finish.

Analyzing QC Samples

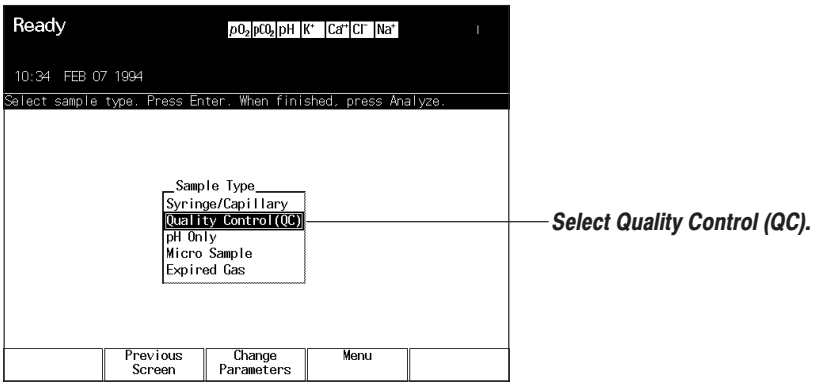
The 800 systems accept QC samples from a syringe or from an aspiration adapter. When you perform routine QC analysis, all parameters available on your system are analyzed. You can specify a panel of parameters to analyze for each sample.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

1. Press **Change Sample Type**.

   The Sample Type menu appears as shown in Figure 2-22.

Figure 2-22. Sample Type Menu



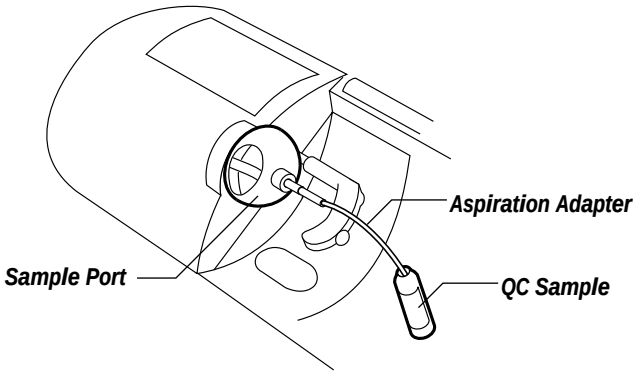
2. Select **Quality Control (QC)** and press **Enter**.

   NOTE: If you are using Bayer Diagnostics controls, you can scan the bar code on the ampule now.

If you want to . . .	*Then . . .*
analyze all parameters for this sample	continue with step 3.
specify a panel of parameters to analyze	a. Select **Change Parameters**. The Parameter Panel appears. b. Select the parameter panel and press **Enter**. c. Continue with step 3.

3. Prepare the sample and insert the device into the sample port. Figure 2-23 shows how to introduce a QC sample using an aspiration adapter.

Figure 2-23. Analyzing a QC Sample With an Aspiration Adapter



CAUTION: To ensure the accuracy of the CO-ox measurement, close the CO-ox cover before pressing Analyze.

4. Press **Analyze**.
5. When prompted, remove the sample device.

   The QC File Information screen appears.

If . . .	*Then . . .*
you already scanned the ampule	the QC File Information screen is complete. Continue with step 7.
Auto ID is on	the system completes the data entry form automatically at the end of analysis. The data entry form remains on the screen until you press Done. Press **Done** to assign the results to the file. The system then displays the final results and prints the report. Continue with step 8.
you did not scan the ampule and Auto ID is off	the QC File Information screen remains displayed until you complete all required fields and press Done. Continue with step 6.

6. Type the file number or scan the bar code from the ampule, and press **Done**.

   When you enter the file number, the system scans the QC database for that file number. If a match is found, the system completes the remaining fields except the Operator ID field.

   Refer to *Entering QC Sample Data*, page 2-43, if you need more information to complete the QC File Information screen.

7. Perform the required action.

Press . . .	*To . . .*
Accept	accept the results into the QC file and update the statistics.
Reject	store the results in the appropriate QC file, but the system does not update the statistics.
Discard	discard the results. The system stores the results in QC File 14. The system does not update the statistics.

8. The system performs a wash at the end of analysis and then returns to the Ready screen. If the system displays the Results screen after the wash finishes, press **Home** to return to the Ready screen.

Procedural Notes

To interrupt sample analysis at any time, press Cancel. The system stops analysis and performs a wash. The Ready screen appears when the wash finishes.

If you press Done before you enter the QC file number in the QC File Information screen, the Unidentified QC File message box appears. Press OK to return to the File ID field and enter the file number.

If you press Done in the QC File Information screen and a field contains incorrect data, the QC Data Mismatch message box appears. Press OK to enter the correct data.

If you scan a bar code other than the QC ampule bar code, the Bar Code Not Recognized message box appears. Press OK. The QC File Information screen appears. Scan the correct QC ampule bar code.

If you scan a bar code for a QC sample that you have not defined in setup, the QC File Not Defined message box appears. Press OK. You must define the QC file for the QC material before you can analyze and store the results.

If you do not press Analyze within 30 seconds while in the Sample Type menu, the system returns to the Ready screen with the default sample type selected.

If you do not complete the QC File Information screen within 5 minutes, the system stores the results in QC File 14, sends a message to the status log, and returns to the Ready screen. You can search for the results in File 14 by sequence number and analysis time. Refer to *Recalling QC Data*, page 2-45.

If the results fall outside of the established control limits, take corrective action according to procedures established for your laboratory. Bayer Diagnostics recommends that you do the following:

- Ensure that the calibration reagents and quality control materials are not expired or deteriorated.

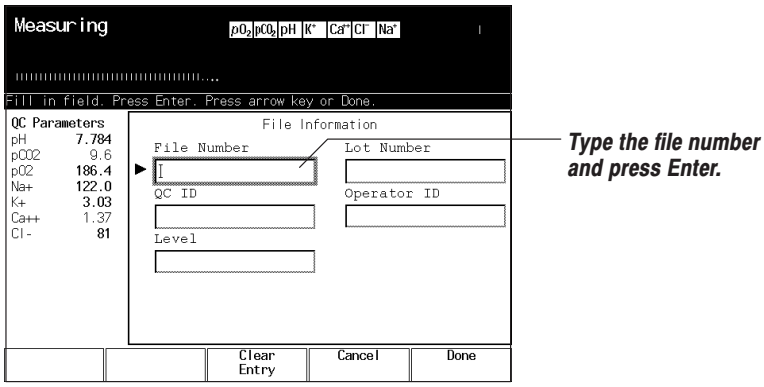
  Visible signs of deterioration include color changes or cloudiness of the reagents or quality control materials.
- Ensure that you followed the operating procedures recommended in this manual.
- Ensure that you handled and sampled the quality control materials according to the procedures recommended by the manufacturer.
- If required, analyze the quality control materials again.

Entering QC Sample Data

Use this procedure to enter QC sample data in the QC File Information screen. You can complete the QC File Information screen using the optional bar code scanner, the keypad or a keyboard, or you can have the system do it automatically.

1. Complete the QC data fields as shown in Figure 2-24.

Figure 2-24. QC File Information Screen



If you . . .	*Then . . .*
use the keypad or keyboard	type the File Number and press **Enter**.
use the optional bar code scanner	scan the bar code label on the QC ampule. **NOTE:** To ensure accurate sample identification, scan QC ampule bar codes only after selecting Quality Control (QC) from the Sample Type screen or when the QC File Information form is displayed.
turn Auto ID on	system automatically determines which file and completes the QC File Information screen. **NOTE:** If the pH or pCO_2 sensor or tHb is disabled or not in calibration, Auto ID does not work.
do not complete the screen	system stores results in QC File 14 and a message that contains the sequence number and date and time of analysis is placed in the status log. Refer to *Editing QC Data*, page 2-48, to move the results to the correct file.

2. Type the Operator ID and press **Done**.

   If you want to change text in the QC File Information screen after you press Done, press **Edit QC Data**. The QC File Information screen reappears. Make your changes and press **Done**.

Procedural Notes

If you do not identify a QC file and you press Done, a message box appears prompting you to identify the QC file. Press OK to return to the QC File Information screen and complete the File Number field.

If you do not identify the QC file and press Done within 5 minutes, the QC sample results are stored in the Discarded Data File. The system returns to the Ready screen. Refer to *Recalling QC Data*, page 2-45, for instructions to recall, edit, and print QC sample data after results are stored.

If you scan a bar code label that is not a QC ampule bar code, a message box appears prompting you to scan a QC ampule bar code. Press OK to return to the QC File Information screen and scan the correct QC ampule bar code label.

Recalling QC Data

Use this procedure to recall the current month's QC sample data and statistics. When the system locates the QC sample data, you can edit the data, print reports, and transmit the data to an LIS or data management system.

You can recall QC data for the previous month by archiving the previous month's QC data and then viewing the data. Refer to *Archiving QC Data* and *Viewing Archived QC Data* in Section 5.

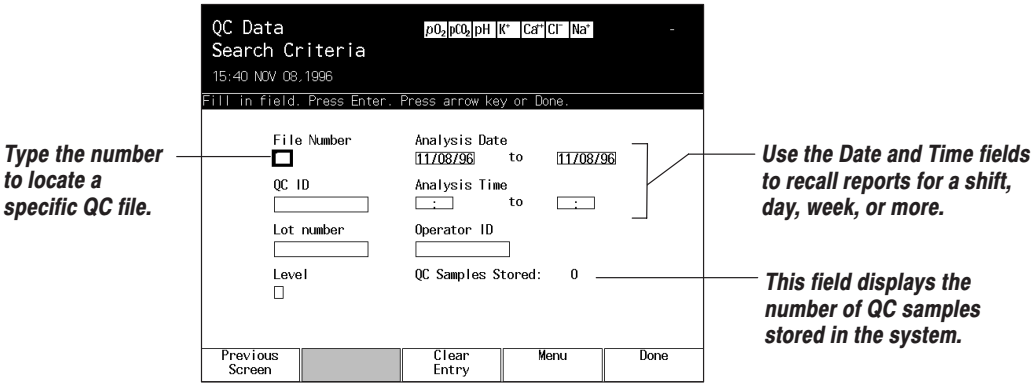
Menu Code

4 ***2***

1. Access the Recall QC Data screen from the Menu screen:
2. Select **4 Data Recall** and press **Enter**.
   a. Select **2 QC Data** and press **Enter**.

      The QC Data Search Criteria screen appears, as shown in Figure 2-25.

Figure 2-25. QC Data Search Criteria Screen



NOTE: The Analysis Date fields contain the current day's date. If you do not complete any other fields, the system recalls all QC samples for this day.

Use this screen to enter the criteria used to search the system for QC sample data. The system uses all entered parameters when searching for patient data. Samples meeting all criteria are recalled. For example, if you enter a QC file number, the system searches for all samples stored in that QC file. If you enter a file number and an analysis date, the system searches only for samples stored in that QC file and analyzed on that date. If you do not complete any of the criteria fields, the system recalls all the QC samples stored in the system.

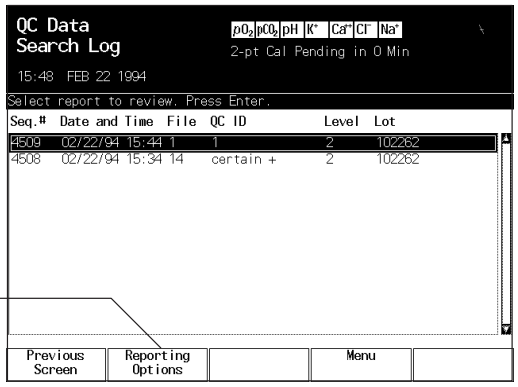
3. Type the search criteria and press **Enter** after you complete each field.

If you want to search . . .	*Then . . .*
for a selected date	type the date in both Analysis Date fields.
from earliest date to the present date	leave the Analysis Date and Analysis Time fields blank.
from the earliest date to a specific date	leave the Analysis Date From field blank, and type the specified date in the Analysis Date To field.
from a specific date to the present date	type the start date in the Analysis Date From field, and type nothing in the Analysis Date To field.
for a specific range of dates	type the start date in the Analysis Date From field, and type the end date in the Analysis Date To field.
by shift or any other specific time period	type the start time in the Analysis Time From field and the end time in the Analysis Time To field.

4. Press **Done**.

If . . .	*Then . . .*
more than one sample is found	the QC Data Search Log screen appears as shown in Figure 2-26. Use the log to select reports you want to view, print, or transmit.
one sample is found	the QC Data Search Result screen appears as shown in Figure 2-27.

Figure 2-26. QC Data Search Log Screen

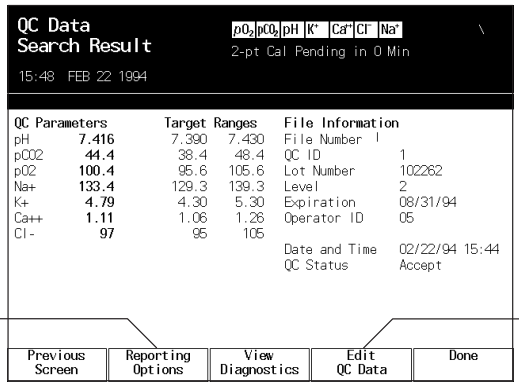


Press Reporting Options to print or transmit a report selected from the log.

5. Select the report that you want to view and press **Enter**.

   The QC Data Search Result screen appears.

Figure 2-27. QC Data Search Result Screen



Press Reporting Options to print or transmit this report.

Press Edit QC Data to edit data for this report.

6. Use this screen to edit, print, or transmit QC reports; to view and print Levey-Jennings Charts; and to print statistical summary reports. When a CO-ox module is attached, you press **More Results** to display the CO-ox parameters.

7. Press **Done**.

If . . .	*Then . . .*
more than one sample is found	the Done Options message box appears: • Select Next Record and press **OK** to view the next report that appears on the log. • Select Previous Record and press **OK** to view the previous report that appears on the log. • Select Search Criteria Screen and press **OK** to view the QC Data Search Criteria screen. • Press **Cancel** to close this message box.
one sample is found	the QC Data Search Criteria screen appears as shown in Figure 2-25.

8. Press **Home** to return to the Ready screen.

Procedural Notes

If no QC sample results are recalled, the No QC Data message box appears. Press OK to return to the QC Data Search Criteria screen.

If the selected sample has a D code or status message associated with it, the View Diagnostics F-key appears. Press View Diagnostics to view the Diagnostics message box. Scroll through the D codes and messages. Press Cancel when you finish.

Editing QC Data

Use this procedure to edit QC data that you recall. You can edit QC data in the following ways:

- move a QC report to a different file.
- change the Accept, Reject, or Discard status.

1. Use the procedure described in *Recalling QC Data*, page 2-45, to locate the QC sample you want to edit.
2. Press **Edit QC Data**.

   The QC File Information screen appears.

If you want to . . .	*Then . . .*
edit data in text fields	a. Move to the field you want to edit. b. Type the changes and press **Enter**.
edit the status of a QC sample	a. Move the cursor to the Status field. b. Press **Change** until the status you want appears.

3. Press **Done**.

   The system displays the QC Data Search Result screen, which now contains the changes you made.
4. Press **Home** to return to the Ready screen.

Procedural Notes

If you change the file, level, or lot number on a QC report, the report moves to the new file number. For example, if you change file number 2 to number 3, the file moves to file 3 when you press Done. The statistics for each file are updated.

If you change the status of a QC sample, the file statistics are adjusted. For example, if you originally discarded the results of a QC sample and you change the status to Accept, the system stores the edited results and updates the Levey-Jennings chart and the file statistics.

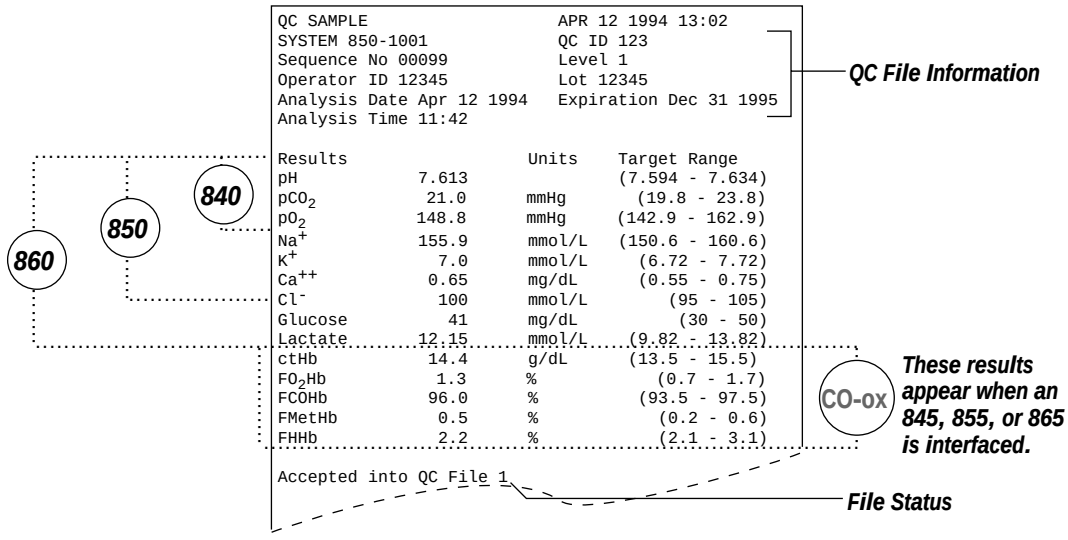
Printing or Transmitting QC Sample Reports

Use this procedure to print or transmit data from the QC Data Search Criteria Log screen or the QC Data Search Result screen.

1. Locate the sample you want as described in *Recalling QC Data*, page 2-45.
2. Press **Reporting Options**.

If you want to . . .	*Then . . .*
print a QC sample report	a. Select Print QC Sample Report and press **Enter**. b. Press **OK**. Refer to Figure 2-28 for an example of a QC sample report.
transmit a QC sample report to an LIS or data management system	a. Select Send Results and press **Enter**. b. Press **OK**.

Figure 2-28. QC Sample Report



3. Press **Home** to return to the Ready screen.

The following result flags can appear on printed reports:

This flag . . .	*Indicates . . .*
*	the measurement did not reach endpoint.
↑	the result is above the upper limit of the target range.

(Continued)

This flag . . .	*Indicates . . .*
↓	the result is below the lower limit of the target range.
↑↑	the result is above the upper limit of the action range.
↓↓	the result is below the lower limit of the action range.
- - -↑	the result is above the upper limit of the measurement range.
- - -↓	the result is below the lower limit of the measurement range.

The following table describes the messages that may appear in QC sample reports on the roll printer:

Message	*Description*
****** = Not in Calibration	Sensor is out of calibration.
* = D5 No Endpoint: __	QC sample analysis did not reach endpoint.
↑ or ↓ = exceeds target range	QC sample result is above or below the target range.
↑↑ or ↓↓ = exceeds action range	QC sample result is above or below the action range.
ACCEPTED INTO QC FILE __	Indicates the QC result status (accepted) and the file number in which the results are stored.
Bubbles Detected In Sample	System detects a non-continuous fluid in the measurement module sample path.
D2 Excessive Drift: __	Sensor drift is beyond predefined limits during a one-point or a two-point calibration.
D38 Temperature Error	System detects an error in the temperature control system.
DISCARDED INTO QC FILE __	Indicates the QC result status (discarded) and the file number in which the results are stored.
REJECTED INTO QC FILE __	Indicates the QC result status (rejected) and the file number in which the results are stored.

Printing Statistical Summary Reports

Use this procedure to print statistical summary reports for the current month's QC data. The statistical summary report includes QC samples analyzed to date.

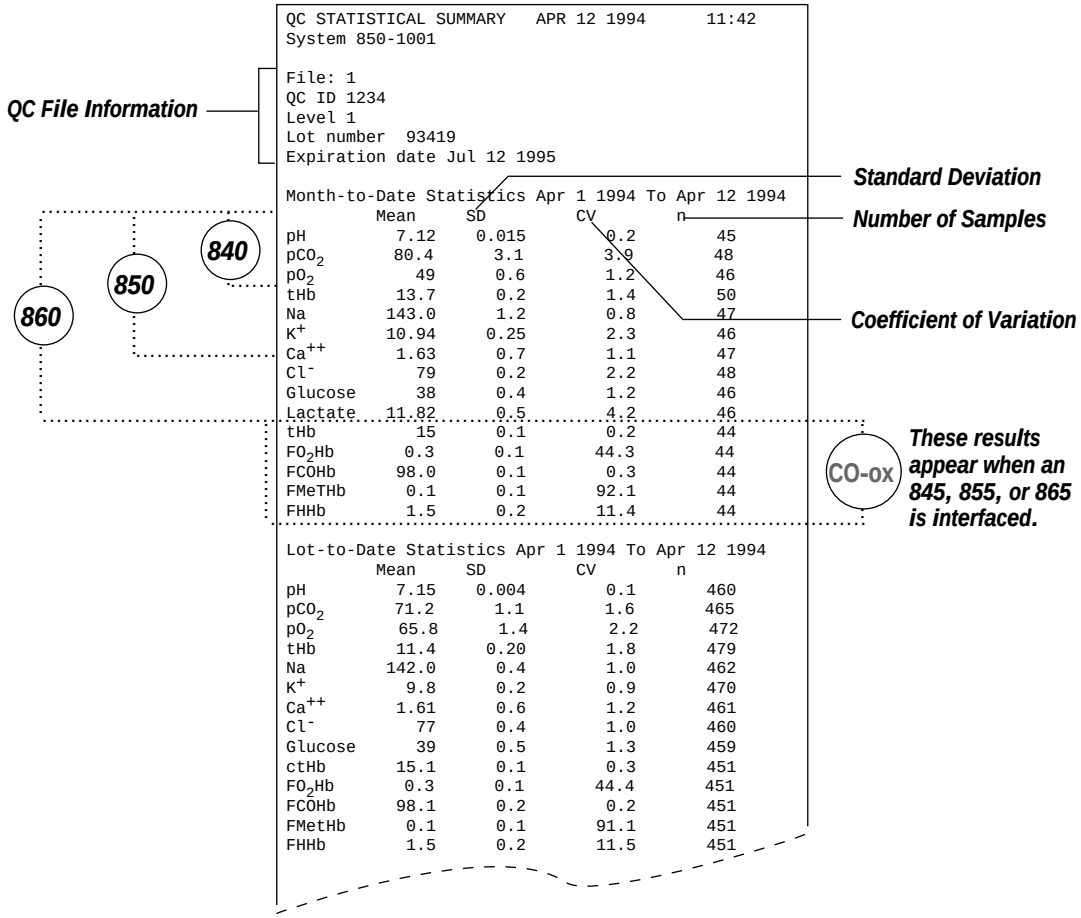
You can print statistical summary reports for the previous month by archiving the previous month's QC data and then printing statistical summary reports for the archived data. Refer to *Archiving QC Data* and *Viewing Archived QC Data* in Section 5.

1. Locate the QC file, as described in *Recalling QC Data*, page 2-45.
2. Press **Reporting Options**.
3. Select Print Statistical Summary and press **Enter**.
4. Press **OK**.

   The statistical summary report prints as shown in Figure 2-29.

   If a QC file has fewer than five data points, the standard deviation and the coefficient of variation do not print.

Figure 2-29. Statistical Summary Report



5. Press **Home** to return to the Ready screen.

Viewing and Printing Levey-Jennings Charts

Use this procedure to view and print Levey-Jennings charts of the current month's QC data.

You can print Levey-Jennings charts for the previous month by archiving the previous month's QC data and then printing Levey-Jennings charts of the archived data. Refer to *Archiving QC Data* and *Viewing Archived QC Data* in Section 5.

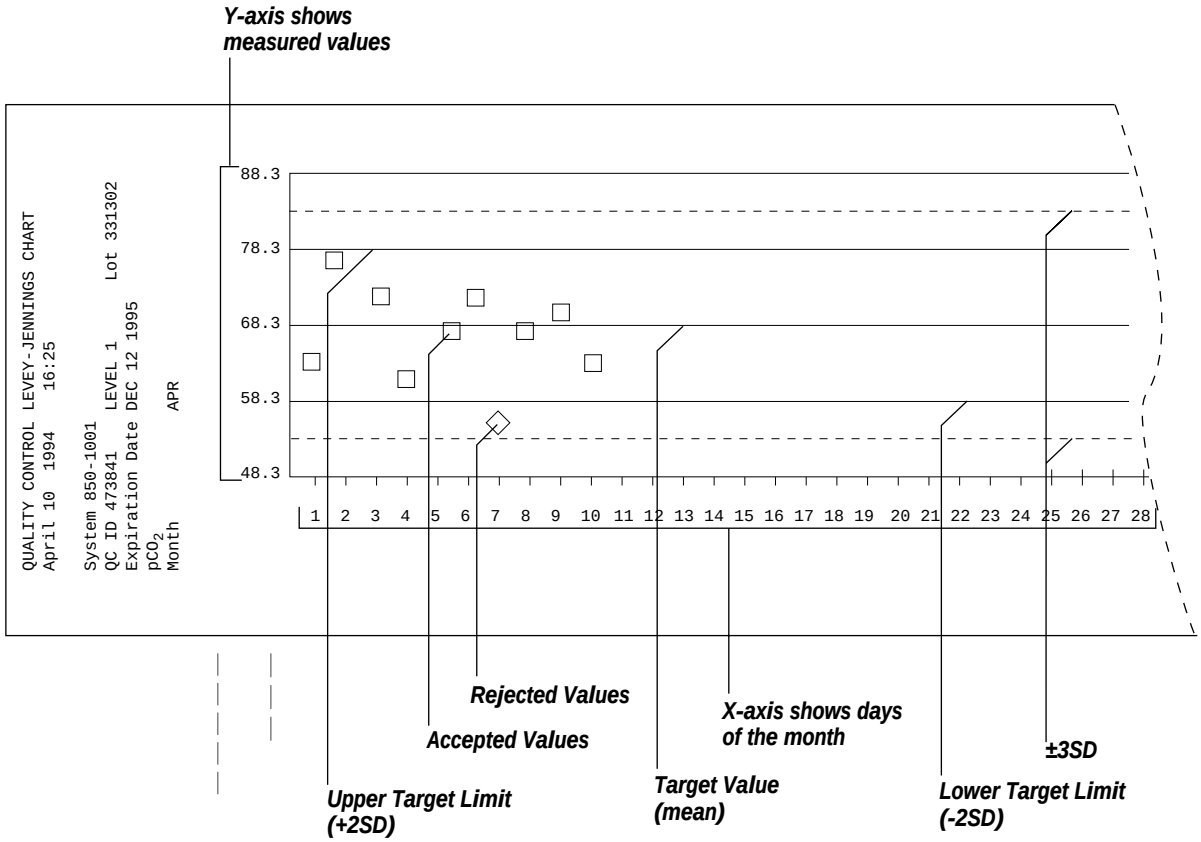
Menu Code
4 ***2***

1. Access the Recall QC Data screen from the Menu screen:
   a. Select **4 Data Recall** and press **Enter**.
   b. Select **2 QC Data** and press **Enter**.
   The QC Data Search Criteria screen appears.
2. Type only the file number and press **Enter**.
   The QC Data Search Criteria Log screen appears.
3. Select **Reporting Options**.

NOTE: You can view the previous month's Levey-Jennings charts before you analyze the first QC sample of the current month. After you analyze the first QC sample of the current month, Levey-Jennings charts contain data only for the current month.

4. Select either Levey-Jennings Current Month or Levey-Jennings Previous Month.
5. Press **OK**.
6. The Levey-Jennings Parameter Selection screen appears.
7. Select the parameter you want to display on the chart and press **Enter**.
8. Press **Done**.
   The Levey-Jennings Chart appears, as shown in Figure 2-30.

Figure 2-30. Levey-Jennings Chart



NOTE: The Levey-Jennings chart for the previous month displays only the data points for QC samples remaining in the file. The Levey-Jennings chart for the current month displays only the data points for QC samples analyzed to date.

9. Perform one of the following tasks.

If you want to . . .	*Then . . .*
print a Levey-Jennings report	press **Print**. The Levey-Jennings report prints.
view a Levey-Jennings report for another parameter	press **Previous Screen**. Select a different parameter and press **Done**.
return to the QC Data Search Criteria screen or the QC Data Search Log	press **Done**.

10. Press **Home** to return to the Ready screen.

Procedural Notes

If the QC Data Search Log contains samples from more than one file and you choose to view a Levey-Jennings chart, the chart that appears is for the file number of the sample that you selected on the log.

The following symbols appear on Levey-Jennings charts:

Symbol	Description
	The results are accepted.
◇	The sample is rejected.
x	The result is beyond the 4 standard deviations range.

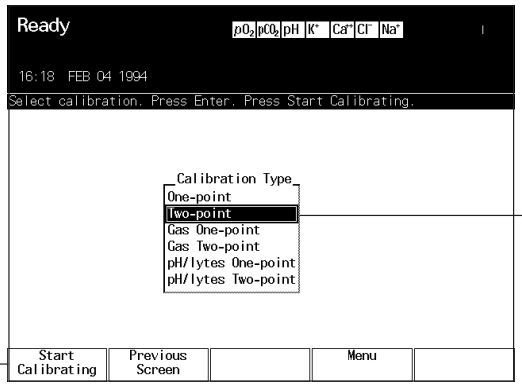
Performing Calibrations from the Analyze Mode

You can perform calibrations from either the Analyze mode or the Menu mode. All calibrations available on the 840, 850, and 860 are also available on systems with the CO-ox module—the 844, 845, 854, 855, 864, and 865.

1. Press **Calibrate**.

   The Calibration Type menu appears, as shown in Figure 2-31.

Figure 2-31. Calibration Type Menu for an 850



2. Select a calibration type and press **Enter**.

   NOTE: The tHb Slope Calibration requires you to enter a value and to introduce the slope reagent. Refer to *Performing tHb Slope Calibrations*, page 2-57, for instructions.

3. Press **Start Calibrating**.
4. Press **Home** to return to the Ready screen.

Procedural Notes

If the Auto Repeat function is on or Flexible Time calibration intervals are selected and a parameter shows excessive drift, the system prints a report and repeats the appropriate calibration for the parameter. Refer to *Selecting Calibration Frequency and Automatic Repeat* in Section 5 for more information about these functions.

If a sensor does not reach endpoint within 90 seconds, the parameter value appears on the screen with an asterisk and the message D5 No Endpoint also appears. The sensor is considered not in calibration until the system completes a successful calibration.

860

The metabolite one-point calibration is available only from the Analyze mode.

Performing Calibrations from the Menu Mode

You can perform calibrations from either the Analyze mode or the Menu mode. All calibrations available on the 840, 850, and 860 are also available on systems with the CO-ox module—the 844, 845, 854, 855, 864, and 865.

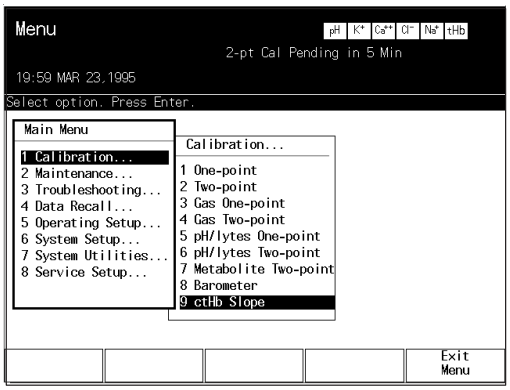
Menu Code

1

1. From the Menu screen, select **1 Calibration** and press **Enter**.

   The Calibration menu appears, as shown in Figure 2-32.

Figure 2-32. Calibration Menu for an 850



2. Select a calibration type and press **Enter**.

   NOTE: The tHb Slope Calibration requires you to enter a value and to introduce the slope reagent. Refer to *Performing tHb Slope Calibrations* on page 2-57 for instructions.

3. Press **Home** to return to the Ready screen. If you do not press Home, the system automatically returns to the Ready screen after 45 seconds.

Procedural Notes

If the Auto Repeat function is turned on or Flexible Time calibration intervals are selected and a parameter shows excessive drift, the system prints a report and repeats the appropriate calibration for the parameter. Refer to *Selecting Calibration Frequency and Automatic Repeat* in Section 5 for more information about these functions.

If a sensor does not reach endpoint within 90 seconds, the parameter value appears on the screen with an asterisk and the message D5 No Endpoint also appears. The sensor is considered not in calibration until the system completes a successful calibration.

860

The metabolite one-point calibration is available only from the Analyze mode.

Performing tHb Slope Calibrations

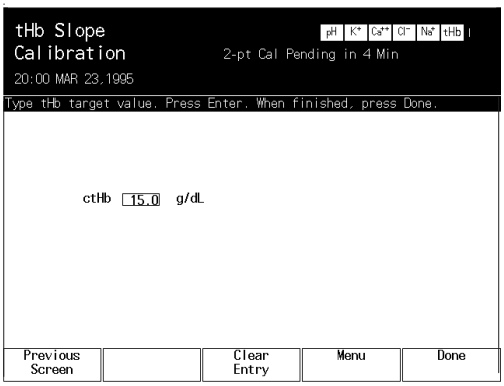
Use this procedure to calibrate the tHb slope for the CO-ox module. You can perform this calibration from either the Analyze mode or the Menu mode.

1. Initiate the tHb slope calibration procedure.

If you are in the . . .	*Then . . .*
Analyze mode	a. Press **Calibrate**. b. Select **tHb Slope.**
Menu mode	a. Select **1 Calibration** and press **Enter**. b. Select **9 tHb Slope** and press **Enter**.

The tHb Slope Calibration screen appears, as shown in Figure 2-33.

Figure 2-33. tHb Slope Calibration Screen



2. Enter the slope value for the slope reagent and press **Enter**.

   NOTE: The last-entered value is displayed. To remove this value, press the **Clear Entry** F-key and enter the new value.

3. Press **Done**.
4. Insert the sample device into the sample port.
5. Press **Analyze**.
6. When prompted, remove the sample device.

   The system performs a wash at the end of the calibration and then returns to the Ready screen.

Procedural Notes

Press Cancel to interrupt a calibration.

The system starts a wash and the Wash screen appears. The system returns to the Ready screen at the end of the wash.

The maximum time between tHb slope calibrations is 90 days. One day before a tHb slope calibration is scheduled, a status message appears on the screen indicating that a calibration is due.

Performing a Barometer Calibration

Use this procedure to calibrate the internal atmospheric pressure sensor to a barometer in your laboratory.

Menu Code

1 ***8***

1. Access the Barometer Calibration screen from the Menu screen:
   a. Select **1 Calibration** and press **Enter**.
   b. Select **8 Barometer** and press **Enter**.
2. Type the correct atmospheric pressure and press **Enter**.
   The acceptable range for atmospheric pressure is 400 – 825 mm Hg (53.0 – 110.0 k Pa).
3. Press **Done** to save the new atmospheric pressure and return to the Ready screen.

Interrupting Calibrations

Press **Cancel** to interrupt a calibration.

Procedural Notes

If you interrupt an automatic calibration, the system will attempt to start the calibration again in 90 seconds. You can delay calibrations for up to 30 minutes beyond the scheduled time. After 30 minutes, the system starts the required calibration. You cannot analyze samples until the required calibration completes.

860

You cannot defer a one-point calibration that is initiated following rapid sampling. You can interrupt or defer the one-point calibration that occurs when the 5 minute timer expires.

The maximum times between automatic one-point and two-point calibrations are 60 minutes and 240 minutes, respectively. Five minutes before an automatic calibration is scheduled, a status message appears on the screen indicating that a calibration is pending.

Recalling Calibration Data

You can print calibration data and send the data to an LIS or a data management system. You cannot edit calibration data.

Menu Code

4 ***4***

1. Access the Recall Calibration Data screen from the Menu screen:
   a. Select **4 Data Recall** and press **Enter**.
   b. Select **4 Calibration Data** and press **Enter**.
2. Select a calibration type and press **Enter**.
3. Type the search criteria and press **Enter**.

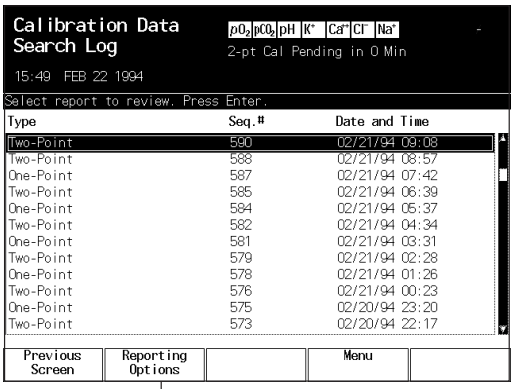
   NOTE: The Calibration Date fields contain the current day's date. If you do not complete any other fields, the system recalls all one-point calibrations for this day.

If you want to search . . .	*Then . . .*
for a selected date	type the date in both Calibration Date fields.
from the earliest date to a specific date	leave the Calibration Date From field blank and type the specific date in the Calibration Date To field.
from a specific date to the present date	type the start date in the Calibration Date From field and leave the Calibration Date To field blank.
by shift or any other specific time period	type the start time in the Calibration Time From field and type the end time in the Calibration Time To field.

4. Press **Done**.

If . . .	*Then . . .*
more than one calibration is found	the Calibration Data Search Log screen appears as shown in Figure 2-34. Continue with step 5.
one calibration is found	the Calibration Data Search Result screen appears, as shown in Figure 2-35. Continue with step 6.

Figure 2-34. Calibration Data Search Log Screen for an 850

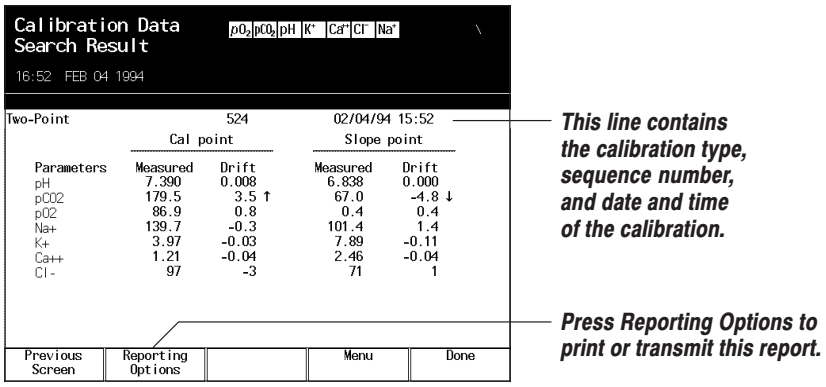


NOTE: The system uses two sequence numbers for two-point calibrations. Only one number appears in the log.

5. Perform the appropriate task at the Calibration Data Search Log.

If you want to . . .	*Then . . .*
view the data for a calibration	select the report you want and press **Enter**. The Calibration Data Search Result screen appears, as shown in Figure 2-35.
print a calibration report	a. Select the report you want. b. Press **Reporting Options**. c. Press **OK.** The calibration report prints, as shown in Figure 2-36.
transmit the results to an LIS or a data management system	a. Select the report you want. b. Press **Reporting Options**. c. Select Send Results and press **Enter**. d. Press **OK**.

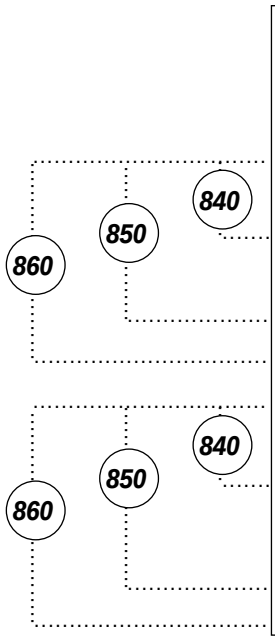
Figure 2-35. Calibration Data Search Result Screen



6. Perform the appropriate task at the Calibration Data Search Result screen.

If you want to . . .	*Then . . .*
print the calibration report	a. Press **Reporting Options**. b. Press **OK**. The calibration report prints, as shown in Figure 2-36.
transmit the results to an LIS or a data management system	a. Press **Reporting Options**. b. Select Send Results and press **Enter**. c. Press **OK**.

Figure 2-36. Two-Point Calibration Report




```
2-POINT CALIBBRATION REPORT      APR 12 1994 13:02
SYSTEM 860-1001
Sequence no  433
Calibration Date             APR 12 1994
Calibration Time             11:42

CAL POINT
                New      Meas     Drift     Units
pH            7.382     7.381    -0.001
pCO2           35.4      34.9      -0.5      mmHg
pO2            85.0      85.0       0.0      mmHg
Na+           140.0     140.9       0.9    mmol/L
K+             4.00      4.00      0.00    mmol/L
Ca++           1.25      1.26      0.01    mmol/L
Cl-             100        99        -1    mmol/L
Glucose           0         0         0     mg/dL
Lactate        0.00      0.02         0    mmol/L
pAtm                      755                mmHg

SLOPE POINT
                New      Meas     Drift     Units
pH            6.838     6.839     0.001
pCO2           70.8      71.3       0.5      mmHg
pO2             0.0      -0.1      -0.1      mmHg
Na+           100.0     100.3       0.3    mmol/L
K+             8.00      8.04      0.04    mmol/L
Ca++           2.50      2.52      0.02    mmol/L
Cl-              70        70      0.00    mmol/L
Glucose         180       180         0     mg/dL
Lactate        0.00      0.02         0    mmol/L
```

Atmospheric pressure appears on all systems

7. Press **Done** when you finish.

If . . .	*Then . . .*
more than one report is found	the Done Options message box appears: • Select Next Record and press **OK** to view the next report that appears on the log. • Select Previous Record and press **OK** to view the previous report that appears on the log. • Select Search Criteria Screen and press **OK** to view the Calibration Data Search Criteria screen. • Press **Cancel** to close this message box. The Search Results screen appears.
one sample is found	the Calibration Data Search Criteria screen appears.

Procedural Notes

If the selected sample has a D code or status message associated with it, the View Diagnostics F-key appears. Press View Diagnostics to view the Diagnostics message box.

The following result flags can appear on printed reports:

This flag . . .	*Indicates . . .*
*	the measurement did not reach endpoint.
↑	the calibration is above the upper drift limit.
↓	the calibration is below the lower drift limit.
- - -↑	the result is above the upper limit of the measurement range.
- - -↓	the result is below the lower limit of the measurement range.

The following table describes the messages that may appear in calibration reports on the roll printer:

Message	*Description*
↑ or ↓ = D2 Excessive Drift: __	Sensor drift is beyond predefined limits during a one-point or a two-point calibration.
* = D5 No Endpoint: __	Calibration did not reach endpoint.
D3 Slope Error: __	Sensor slope is beyond predefined limits during a two-point calibration.
D4 Offset Error: __	Sensor offset is beyond predefined limits during a one-point or a two-point calibration.
D22 Barometric Pressure Error (for gas cals)	Signal from the barometer detects atmospheric pressure beyond predefined limits.
D50 Glucose Sensor Error	System detects an open connection in the glucose sensor.
D51 Lactate Sensor Error	System detects an open connection in the lactate sensor.

3 Maintaining the System

Recording Maintenance Tasks

Use this procedure to view pending maintenance tasks and record completed maintenance tasks in the maintenance log.

Menu Code

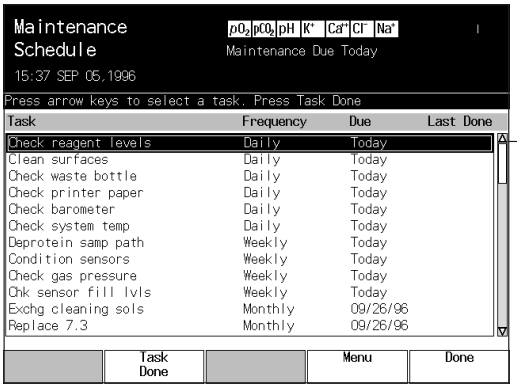
2 ***4***

1. Access the Maintenance Schedule screen from the Menu screen:
   a. Press **2 Maintenance** and press **Enter**.
   b. Press **4 View Schedule** and press **Enter**.

   The Maintenance Schedule screen appears as shown in Figure 3-1.

   Tasks due for the current date appear at the top of the scroll list.

Figure 3-1. Maintenance Schedule Screen



Highlight the task you want to record and press Task Done.

2. Use the arrow keys to highlight the task you want to record as completed.
3. Press **Task Done**.

   The Maintenance Task Done dialog box appears.
4. Enter your operator ID and press **OK**.

   The Maintenance Schedule screen reappears with the updated task list.
5. Select another task to record or press **Done** to return to the Menu screen.

Procedural Notes

Record maintenance tasks on the day you complete them. If you perform a task on Monday but record it on Tuesday, the system will list the task as being completed on Tuesday, not Monday.

Printing the Maintenance Schedule Report

Use this procedure to print a Maintenance Schedule Report from the Maintenance Schedule screen. The report lists all the maintenance tasks for the system model. The tasks are sorted by frequency. Tasks due for the current date appear at the top of the report. The Due field displays the date on which the task is due next. The Date/Time Done field displays the date and time the maintenance task was last recorded as complete. If a task was not performed, the Date/Time field is blank.

Menu Code

2 ***4***

1. Access the Maintenance Schedule screen from the Menu screen:
   a. Press **2 Maintenance**
   b. Press **4 View Schedule**.
2. Press **Print**.
3. Press **Done** to return to the Menu screen.

Recalling the Maintenance Log

Use this procedure to view and print the list of completed maintenance tasks for the current or the previous month.

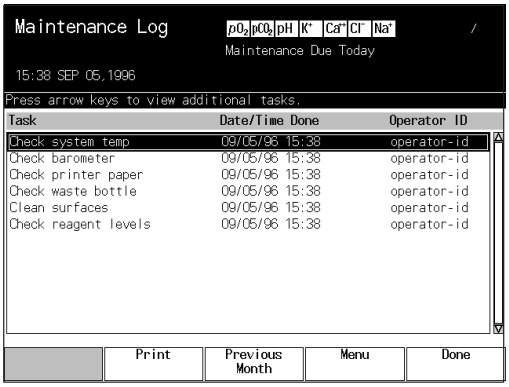
Menu Code

4 *3*

1. Access the Maintenance Log screen from the Menu screen:
   a. Press **4 Data Recall** and press **Enter**.
   b. Press **3 Maintenance Log** and press **Enter**.

   The Maintenance Log screen appears as shown in Figure 3-2.

Figure 3-2. Maintenance Log Screen



2. Use the arrow keys to scroll through the task list.
3. Press **Previous Month** to view tasks completed in the previous month.
4. Press **Done** to return to the Menu screen.

Procedural Notes

The system only keeps two months of data online. At Autoclean time on the first day of each month, the data is rotated and the oldest data is erased.

Daily Maintenance

The daily maintenance schedule is based on analyzing 30 samples per day, unless otherwise noted. If your laboratory analyzes more than 30 samples per day, perform daily maintenance more frequently.

Cleaning the Exterior Surfaces

Materials required:

- 10% solution of household bleach

NOTE: Dilute household bleach (5.25% sodium hypochlorite) 1:10 with reagent quality water.

- reagent-quality water[44]
- lint-free tissues or swabs

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

- Wipe with a 10% solution of household bleach all exterior surfaces, including:
- the sample entry components and the drip tray
- the waste area

NOTE: Do not insert swabs into the sample port or spray anything into the measurement module.

1. Rinse the exterior surfaces with reagent-quality water.

NOTE: Bayer Diagnostics recommends using reagent-quality water in accordance with NCCLS guidelines. Refer to the *Water Quality Technical Bulletin* included at the back of this manual.

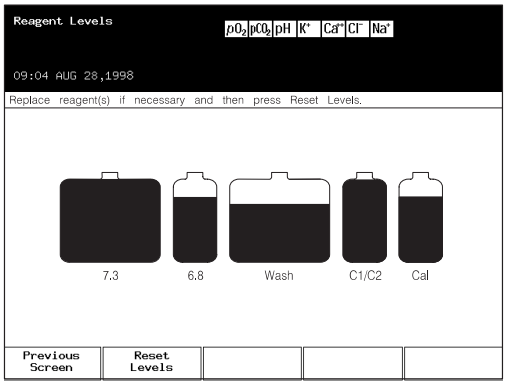
2. Clean spills around the roller cages:
   a. Remove the roller cage as described in *Replacing a Roller Cage*, page 3-96.
   b. Clean the roller cage and the roller cage shaft with a 10% solution of household bleach.
   c. Rinse with reagent-quality water and dry thoroughly.
   d. Reinstall the roller cage.

Checking the Reagents

WARNING Wear safety glasses, gloves and a laboratory coat when handling the reagents.

Check the reagent levels and expiration dates for the 7.382 Buffer, 6.838 Buffer, Wash G/L Zero, Cleaning Solution, and Cal G/L reagents. On the Ready screen, press **Enter** to display the Reagent Levels screen as shown in Figure 3-3.

Figure 3-3. Reagents Levels Screen



View the reagent levels. Replace the bottles if they are empty, nearly empty, or are at the expiration date as described in *Replacing the Reagent Bottles*, page 3-65.

Checking the Printer Paper

Check the amount of paper on the roll. A pink line on the paper indicates that the roll is nearly empty. Replace the paper if the roll is empty or nearly empty as described in *Replacing the Printer Paper*, page 3-66.

Checking the Waste Bottle Volume

Check the fluid volume in the waste bottle. Empty the waste bottle if it is at or near the waste full line as described in *Emptying the Waste Bottle*, page 3-45.

Checking the Sample Path Temperature

Menu Code
3 ***2***

1. Access the Temperature screen from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **2 Temp/pAtm** and press **Enter**.
2. Press **Start Test**.
3. Press **Stop Test**.
4. Check the screen to verify that the sample temperature is 37 ±0.15°C for the base model and 37 ±0.35°C for the CO-ox module.

NOTE: The 37°C temperature point is NIST traceable.

5. Press **Exit Test**.

Checking the Barometer

Use this procedure to check the atmospheric pressure detected by the 800 system.

Menu Code
1 ***8***

1. Access the Barometer Calibration screen from the Menu screen:
   a. Select **1 Calibration** and press **Enter**.
   b. Select **8 Barometer** and press **Enter**.

2. Compare the displayed atmospheric pressure to your laboratory's barometer reading.

If the displayed atmospheric pressure is . . .	***Then . . .***
correct	press **Done**.
incorrect	a. Type the correct atmospheric pressure and press **Enter**. b. Press **Done** to save the new atmospheric pressure and return to the Ready screen. c. Perform a gas two-point calibration.

Twice Weekly Maintenance

The twice weekly maintenance schedule is based on analyzing 30 samples per day, unless otherwise noted. If your laboratory analyzes more than 30 samples per day, perform twice weekly maintenance more frequently.

Analyzing High G/L

Use this procedure to verify the performance of the glucose and lactate biosensors.

Materials required:

- High G/L ampule
- aspiration adapter

1. Perform a successful two-point calibration.
2. Prepare the High G/L ampule and insert an aspiration adapter into the sample port and into the ampule.
3. Press **Analyze**.
4. When prompted, remove the sample.
5. Type the required information in the Patient Information screen and press **Done**.
6. Review the results.

   If the glucose or lactate results are below the values recommended on the High G/L package insert, replace the affected biosensor as described in *Replacing the Glucose and Lactate Biosensors*, page 3-86.

Weekly Maintenance

The weekly maintenance schedule is based on analyzing 30 samples per day, unless otherwise noted. If your laboratory analyzes more than 30 samples per day, perform weekly maintenance more frequently.

Use this procedure to clean the sample path with deproteinizer once a week or every 210 samples. Deproteinizing removes protein buildup from the sample path.

Deproteinizing the Sample Path

NOTE: If your system has a CO-ox module, follow the procedure described for the appropriate base model. For example, information identified for an 860 also applies to an 865.

Materials required:

- deproteinizer
- aspiration adapter

860

- glucose and lactate test/blank sensors (TB4)

1. Prepare the deproteinizer as directed on the package.

Menu Code
2 1

2. Access the Deproteinize screen from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **1 Deproteinize** and press **Enter**.

CAUTION: Do not expose the glucose and lactate biosensors to deproteinizer. Replace the biosensors with the test/blank sensors (TB4) before deproteinizing. Reinstall the biosensors within 2 hours.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

3. Take the appropriate action.

If you have an . . .	*Then . . .*
840 or 850	go to step 4.
860	a. Remove the glucose and lactate biosensors. b. Install the test/blank sensors. c. Go to step 4.

4. Invert the deproteinizer vial several times to mix.

5. Insert an aspiration adapter into the sample port and insert the other end into the deproteinizer vial, or decant the deproteinizer into a syringe and insert the syringe into the sample port.
6. Press **Analyze**.
7. When prompted, remove the adapter or syringe.
8. Wait 5 minutes for the deproteinizing cycle to finish.
9. Take the appropriate action.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

860

NOTE: As you reinstall the biosensors, ensure that the biosensors are in the correct location. Visually verify that you align the contacts on the biosensors with the contacts in the measurement module. You can slide the remaining sensors to the right to create more space.

If . . .	*Then . . .*
you want to condition the sensors	press **Yes**. The Conditioning screen appears. Go to step 2 of *Conditioning the Sensors*, page 3-14.
you do not want to condition the sensors	a. Press **No**. A wash starts. When the wash finishes, a message box appears prompting you to perform a two-point calibration. b. On the 860 remove the test/blank sensors and reinstall the biosensors. c. Press **Yes**.

Procedural Notes

Press **Cancel** to stop deproteinizing. The system performs a wash and then displays the Calibrate System message box.

Use this procedure to condition the sensors once a week or after 210 samples. Conditioning cleans and conditions the glass membranes of the pH and sodium sensors.

Conditioning the Sensors

Materials required:

- conditioner
- syringe

860

- glucose and lactate test/blank sensors (TB4)

NOTE: If your system has a CO-ox module, follow the procedure described for the appropriate base model. For example, information identified for an 860 also applies to an 865.

Menu Code
2 ***2***

1. Access the Condition screen from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **2 Condition** and press **Enter**.

860 **CAUTION:** Do not expose the glucose and lactate biosensors to the conditioner. Replace the biosensors with the test/blank sensors (TB4) before conditioning. Reinstall the biosensors within 2 hours.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

2. Take the appropriate action.

If you have an . . .	*Then . . .*
840 or 850	go to step 3.
860	a. Remove the glucose and lactate biosensors. b. Install the test/blank sensors. c. Go to step 3.

3. Draw the conditioner solution into a syringe.
4. Insert the syringe into the sample port.
5. Press **Analyze**.
6. When prompted, remove the syringe.
7. Wait 10 minutes for the conditioning cycle to finish.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

860 **NOTE:** As you reinstall the biosensors, ensure that the biosensors are in the correct location. Visually verify that you align the contacts on the biosensors with the contacts in the measurement module. You can slide the remaining sensors to the right to create more space.

860 8. Remove the glucose and lactate test/blank sensors and reinstall the glucose and lactate biosensors as described in *Replacing the Glucose and Lactate Biosensors*, page 3-86.

9. Press **Yes** to perform a two-point calibration.
10. Analyze a minimum of two levels of quality control material to verify sensor performance.

Procedural Notes

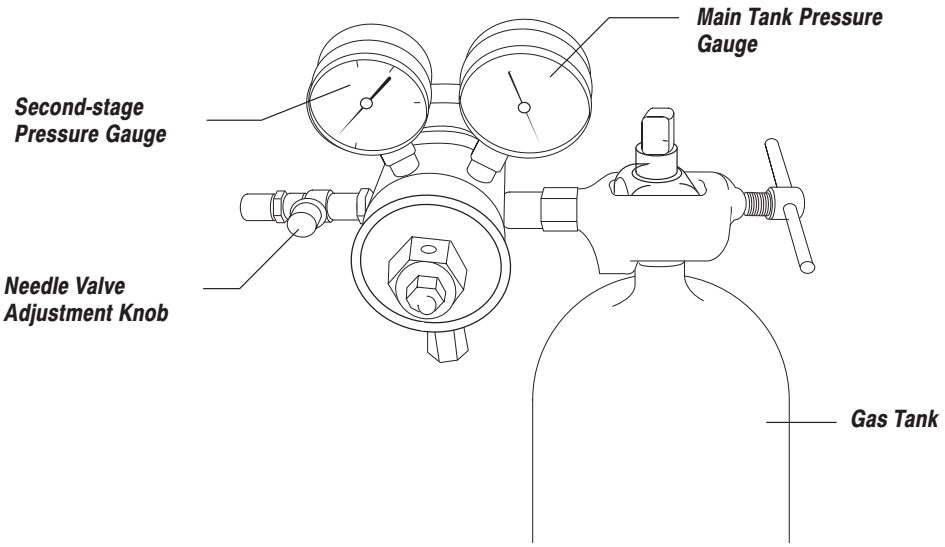
Press **CANCEL** to stop conditioning. The system performs a wash and then displays the Calibrate System message box.

Checking the Gas Tank Pressures

The main tank pressure must be higher than 300 psi. The second stage pressure must be 3 to 5 psi.

1. Check the main tank and second-stage pressure for each gas tank by looking at pressure gauges on the gas tank regulator as shown in Figure 3-4.

Figure 3-4. Calibration Gas Tank Regulator



2. If the main tank pressure is below 300 psi, verify that the gas tank is open.
3. If the main tank is open and the pressure is still below 300 psi, replace the tank as described in *Replacing the Gas Tanks*, page 3-90.

Checking the Solution Levels in the Sensors

Use this procedure to ensure that the sensors contain fill solution to the levels described in Figure 3-5.

Figure 3-5. Fill Solution Levels

Sensor	Fill Solution Level
pH, K^+, Cl^-, and Ca^{++}	nearly full and with a bubble at the top
Na^+	to the top
Reference	to the fill line

NOTE: The pO_2 and pCO_2 sensors do not require you to maintain them, even though they have fill solution. Slight discoloration of the fill solution in the pO_2 and pCO_2 sensors is normal.

860

NOTE: The glucose and lactate biosensors do not require fill solution.

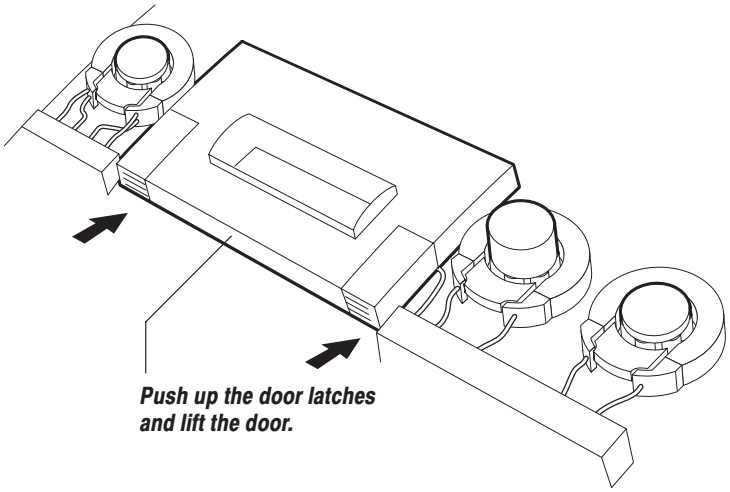
BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code

2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Open the measurement module door as shown in Figure 3-6:
   a. Push up the latches on the measurement module door.
   b. Lift the door.

Figure 3-6. Opening the Measurement Module Door



3. Verify that the reference sensor fill solution is not below the fill line. Refer to *Filling the Reference Sensor*, page 3-69.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

4. If necessary, fill the sensor as described in *Filling the Reference Sensor,* page 3-69.
5. Verify that the pH, K^+, Cl^-, and Ca^{++} sensors are almost full with only a bubble at the top and that the Na^+ sensor is completely full.

   If any sensor is not properly filled, replace the fill solution as described in *Filling the Measurement Sensors*, page 3-80.
6. Close the measurement module door.
7. Press **Continue** and allow the system to warm up.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

If . . .	***Then . . .***
you want to perform a two-point calibration	press **Yes**.
you do not want to perform a two-point calibration	a. Press **No**. b. Press **Home** to return to the Ready screen.

Monthly Maintenance

The monthly maintenance schedule is based on the expiration date of the opened reagents.

Exchanging the Cleaning Solutions

Effective cleaning is accomplished by alternating Cleaning Solution 1 (C1) and Cleaning Solution 2 (C2) each month.

If . . .	*Then remove it and . . .*
C1 is on your system	replace it with C2.
C2 is on your system	replace it with C1.

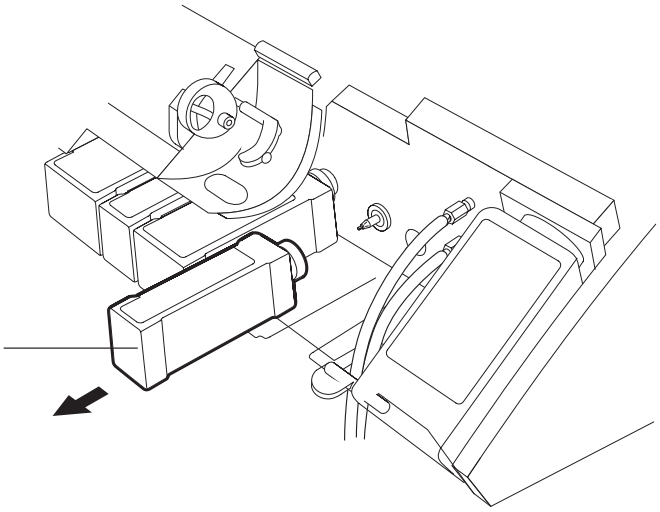
WARNING Wear safety glasses, gloves, and a laboratory coat when handling the reagents.

1. At the Ready screen, press **Enter**.

   The Reagent Levels screen appears.

2. Remove the cleaning solution bottle from the reagent manifold as shown in Figure 3-7.

Figure 3-7. Removing the Cleaning Solution from an 860



3. Write the date installed in the space provided on the new cleaning solution bottle.

NOTE: Do not remove or tighten the cap that contains the reagent septum. Removing or tightening the cap damages the integrity of the reagent septum.

4. Remove the plug from the cap of the new cleaning solution bottle.
5. Insert the cleaning solution bottle into position on the reagent manifold.
6. Push the bottle to ensure that it fits tightly on the reagent fitting.
7. Press **Reset Levels**.

   The Reset Levels screen appears.
8. Select C1/C2 and press **Done**.

Replacing 7.3/CO-ox Zero and Cal G/L Reagents

Use this procedure to discard and replace the 7.3/CO-ox Zero and Cal G/L reagents if they are opened and installed on the system for 30 days.

Materials required:

- 7.3/CO-ox Zero (7.382 Buffer)
- Cal G/L

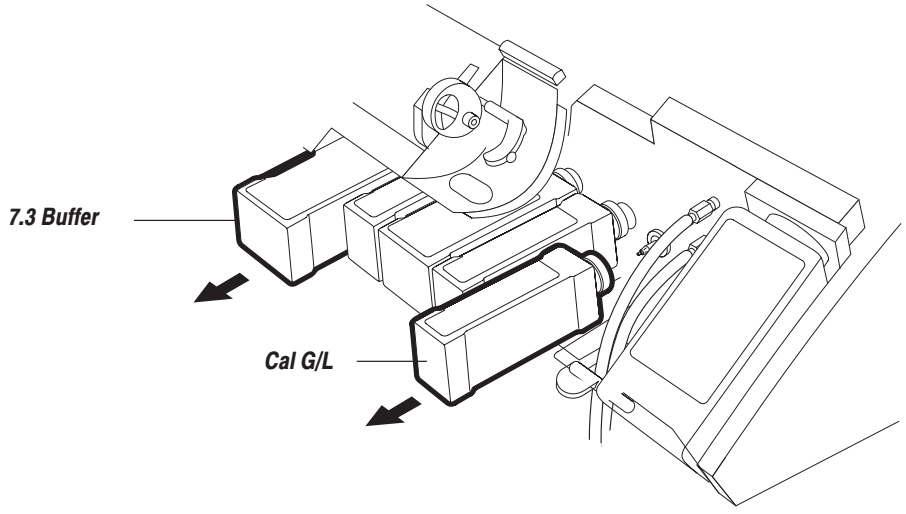
860

WARNING Wear safety glasses, gloves, and a laboratory coat when handling the reagents.

1. At the Ready Screen, press **Enter**.

   The Reagent Levels screen appears.
2. Remove the reagent bottles from the reagent manifold as shown in Figure 3-8 for an 860 system.

Figure 3-8. Removing the 7.3/CO-ox Zero and Cal G/L Reagents



3. Write the date installed in the space provided on the new reagent bottles.

NOTE: Do not remove or tighten the cap that contains the reagent septum. Removing or tightening the cap damages the integrity of the reagent septum.

4. Remove the plugs from the caps of the new reagent bottles.
5. Insert the new reagent bottles into position on the reagent manifold.
6. Push the bottles to ensure that they fit tightly on the reagent fitting.
7. Press **Reset Levels**.

   The Reset Levels screen appears.
8. Select the reagent(s) that you replaced and press **Done**.

   A prime sequence starts followed by a wash sequence. When the wash sequence finishes, the Ready screen appears.
9. Perform a two-point calibration.
   a. Press **Calibrate**.
   b. Select Two-point and press **Enter**.
   c. Press **Start Calibration**.

Procedural Notes

Perform a two-point calibration after changing the reagents to ensure that the reagents are acceptable and the system is functioning properly. You can analyze quality control materials with the new reagents and compare the results with the previous QC results after the system is recalibrated.

Inspecting the Capillary Seal

1. Remove the capillary seal as described in *Replacing the Capillary Seal*, page 3-100.
2. Inspect the seal for damage such as abrasion and cuts. Replace the capillary seal if the seal is damaged.
3. Reinstall the capillary seal.

Bimonthly Maintenance

Perform the following procedures every 2 months. The bimonthly maintenance schedule is based on analyzing 30 samples per day, unless otherwise noted. If your laboratory analyzes more than 30 samples per day, perform bimonthly maintenance more frequently.

Replacing 6.838 Buffer and Wash G/L Zero Reagents

Use this procedure to discard and replace the 6.838 Buffer and Wash G/L Zero reagents if they are opened and installed on the system for 60 days.

Materials required:

- 6.838 Buffer
- Wash G/L Zero

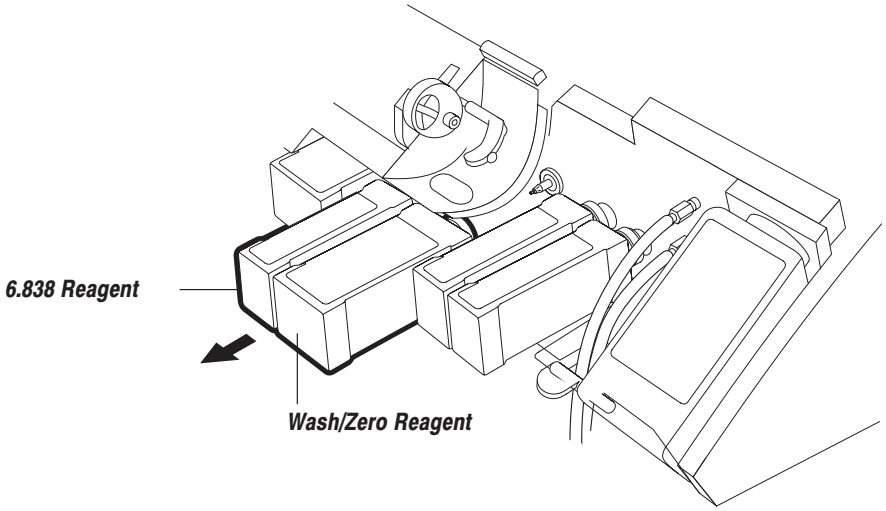
WARNING Wear safety glasses, gloves, and a laboratory coat when handling the reagents.

1. At the Ready screen, press **Enter**.

   The Reagent Levels screen appears.

2. Remove the reagent bottles from the reagent manifold as shown in Figure 3-9 for an 860 system.

Figure 3-9. Removing the 6.838 Buffer and Wash G/L Zero Reagents



3. Write the date installed in the space provided on the new reagent bottles.

NOTE: Do not remove or tighten the cap that contains the reagent septum. Removing or tightening the cap damages the integrity of the reagent septum.

4. Remove the plugs from the caps of the new reagent bottles.
5. Insert the new reagent bottles into position on the reagent manifold.
6. Push the bottles to ensure that they fit tightly on the reagent fittings.
7. Press **Reset Levels**.

   The Reset Levels screen appears.
8. Select the reagent(s) that you replaced and press **Done**.

   A prime sequence starts followed by a wash sequence. When the wash sequence finishes, the Ready screen appears.
9. Perform a two-point calibration.
   a. Press **Calibrate**.
   b. Select Two-point and press **Enter**.
   c. Press **Start Calibration**.

Procedural Notes

Perform a two-point calibration after changing the reagents to ensure that the reagents are acceptable and the system is functioning properly. You can analyze quality control materials with the new reagents and compare the results with the previous QC results after the system is recalibrated.

Replacing the Sample Tubing

Materials required:

- sample tubing

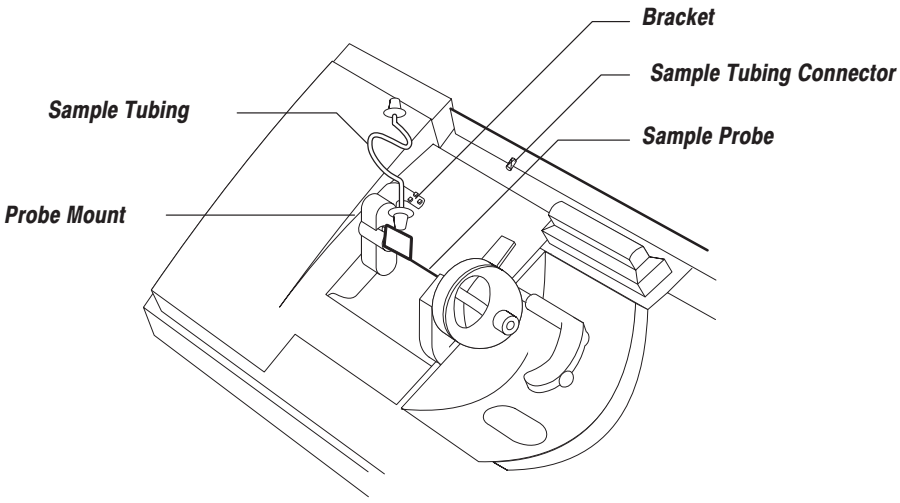
BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code

2 7

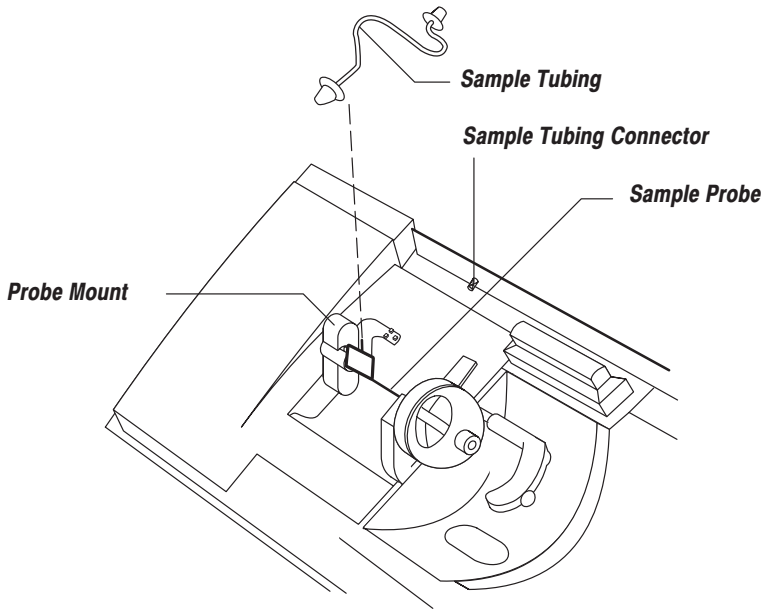
1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Disconnect the sample tubing from the connector on the measurement module.
3. Disconnect the sample tubing from the probe mount.
4. Rotate the sample tubing toward you as shown in Figure 3-10.

Figure 3-10. Rotating the Sample Tubing



5. Disconnect the tubing from the sample probe as shown in Figure 3-11.

Figure 3-11. Removing the Sample Tubing



6. Discard the tubing according to your laboratory's biohazard protocol.
7. Orient the new sample tubing as shown in the diagram on the system.
8. Connect the new sample tubing to the sample probe.
9. Place the sample tubing in the bracket on the probe mount.
10. Rotate the sample probe toward the system.

11. Connect the sample tubing to the sample tubing connector on the measurement module.
12. Press **Continue**.

    A wash sequence starts. When the wash sequence sequence finishes, a message box appears prompting you to perform a two-point calibration.
13. Press **Yes** to perform a two-point calibration.

Quarterly Maintenance

Perform the following procedures every 3 months. The quarterly maintenance described in this section is based on analyzing 30 samples per day. If your laboratory analyzes more than 30 samples per day, perform this maintenance more frequently.

Cleaning the CO-ox Sample Chamber

Materials required:

- lint-free tissue or lint-free swabs
- lens paper
- reagent quality water
- dilute cleaning solution (do not use bleach, alcohol, or abrasive powder)
- sample chamber gasket and support
- 0.16-inch diameter clot-removal line
- bubble trap seal, if necessary

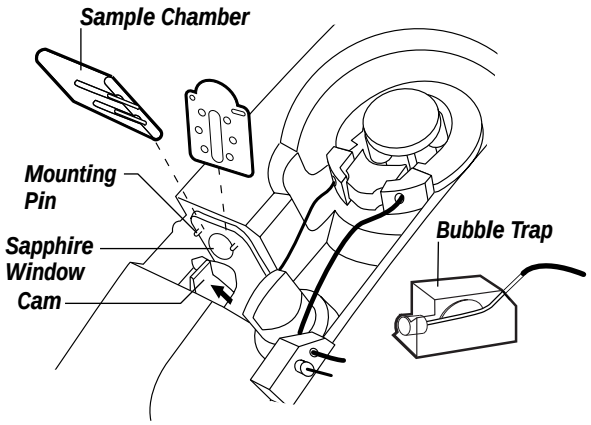
BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code

2 ***7***

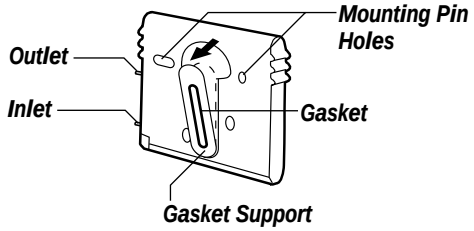
1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Disconnect the tubing and the bubble trap from the sample chamber.
3. Remove the sample chamber as shown in Figure 3-12:
   a. Turn the tab on the cam to the left to loosen the sample chamber.
   b. Grasp the sample chamber by the edges and pull it off of the mounting pins.
   c. Remove metal plate installed behind the sample chamber.

Figure 3-12. Removing the Sample Chamber



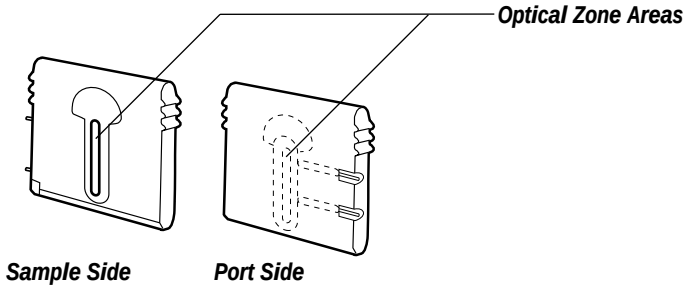
4. Remove the gasket and support:
   a. Slide your finger under the flat metal support of the gasket.
   b. Lift the gasket and support from the sample chamber.

Figure 3-13. Removing the Gasket



⚠ **CAUTION:** Do not touch the optical zone (front or back area enclosed by the gasket) of the sample chamber with your fingers.

Figure 3-14. Optical Zone



5. Push a 0.016-inch diameter clot-removal line into the metal tubing of the inlet and outlet ports of the sample chamber.
6. Flush the inlet and outlet ports to remove any clots or debris:

a. Fill a syringe with reagent-quality water.

b. Attach a capillary adapter or a piece of 0.016-inch diameter sample tubing to the syringe.

c. Attach the tubing or capillary adapter to the port and flush the water through the port.

7. Clean the glass sapphire window with a lint-free tissue or swab soaked with cleaning solution. Wash the window with reagent-quality water.

8. Blot the exterior of the window dry with lint-free tissue.

9. Install a new gasket on the sample chamber:

   a. Soak the gasket and the grooved area of the sample chamber with reagent quality water to facilitate the installation.

   b. Wipe both sides with a lint-free tissue soaked in cleaning solution.

   c. Wipe both sides with a lint-free tissue soaked in reagent-quality water.

   d. Blot both sides dry with lint-free tissue.

10. Clean the metal plate:

    a. Wipe both sides of the plate with a lint-free tissue soaked in cleaning solution.

    b. Wipe both sides with a lint-free tissue soaked in reagent-quality water.

    c. Blot both sides dry with lint-free tissue.

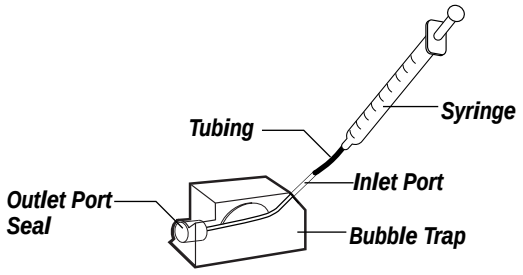
11. Clean the bubble trap:

    a. Visually inspect the bubble trap seal on the outlet port of the bubble trap. Replace the seal if it is torn or frayed.

    b. Push a 0.016-inch diameter clot-removal line into the metal tubing of the outlet port of the bubble trap.

    c. Flush the bubble trap by injecting reagent-quality water into the metal port using a syringe and a separate piece of tubing or capillary adapter as shown in Figure 3-15**.**

Figure 3-15. Cleaning the Bubble Trap



d. Wipe the exterior of the bubble trap with a lint-free tissue soaked in reagent quality water.

e. Blot the exterior dry with lint-free tissue.

12. Inspect the tubing.
    a. If the tubing is damaged, or is stretched or loose at the connection, replace the tubing as described in *Replacing the CO-ox Sample Tubing* on page 3-37.
    b. If there is an obstruction in the tubing, remove the sample tubing.
    c. Push a 0.016-inch diameter clot-removal line through the sample tubing from back to front, opposite the direction of sample flow.
    d. Reinstall the sample tubing.

CAUTION: Ensure that the area between the metal plate and the sapphire window is free of dust or debris.

13. Reinstall the metal plate into the sapphire window by aligning onto the mounting pins.
14. Reinstall the sample chamber:
    a. Connect the bubble trap to the sample chamber inlet port.
    b. Align the mounting pin holes on the sample chamber with the mounting pins.
    c. Turn the tab on the cams to the right until the cams tighten against the sample chamber.
    d. Reconnect the tubing to the sample chamber outlet port.
    e. Reconnect the tubing to the bubble trap inlet port.
15. Press **Continue**.

    A wash sequence starts. When the wash sequence sequence finishes, a message box appears prompting you to perform a two-point calibration.
16. Press **No**.
17. Perform a pH/lytes one-point calibration.
18. Perform a tHb slope calibration.

Cleaning the Hemolyzer

Materials required:

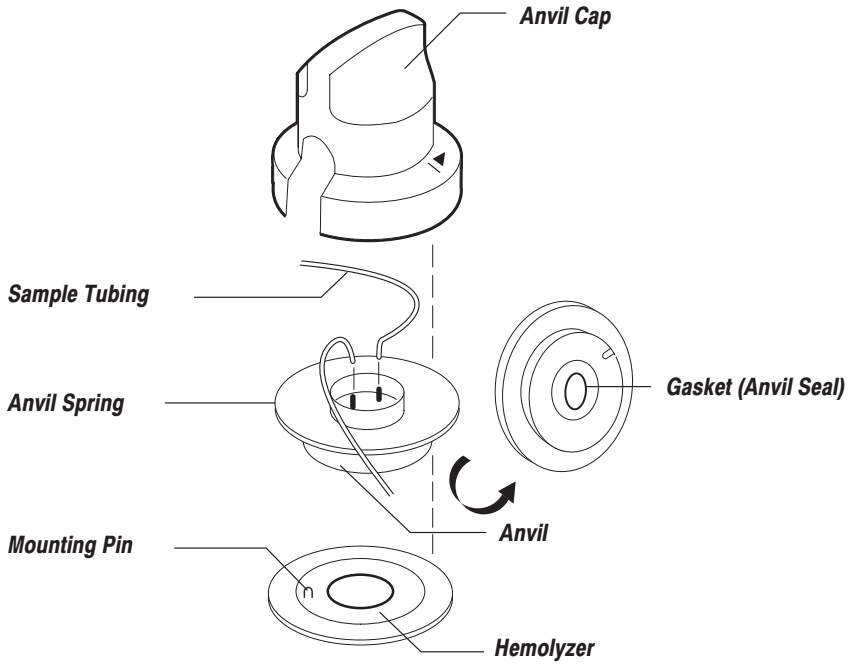
- lint-free tissue or lint-free swabs
- reagent-quality water
- dilute cleaning solution (do not use bleach, alcohol, or abrasive powder)
- hemolyzer gasket

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code
2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Disassemble the hemolyzer as shown in Figure 3-16:

Figure 3-16. Disassembling the Hemolyzer



   a. Remove the anvil cap on the hemolyzer by turning it one quarter-turn counterclockwise.
   b. Disconnect the sample tubing from the anvil.
   c. Pull the anvil and anvil spring away from the mounting pin on the hemolyzer.

d. Lay the anvil on its side.

e. Remove the gasket and discard it according to your laboratory biohazard protocol.

3. Clean the hemolyzer and the anvil:

   a. Clean the hemolyzer with a lint-free tissue soaked in mild cleaning solution.

   b. Wipe the surface with a lint-free tissue soaked in reagent-quality water.

   c. Dry the surface thoroughly.

   d. Repeat steps a through c for the anvil.

4. Reassemble the hemolyzer:

   a. Insert a new gasket in the groove of the anvil.

   b. Place the anvil on the mounting pin. Make sure the anvil is seated on the pin and does not rotate. The anvil spring does rotate.

   c. Reconnect the sample tubing to the anvil.

   d. Reinstall the anvil cap to secure the anvil. Listen for a click, which indicates that the anvil is in place.

   NOTE: The anvil sits loosely on the hemolyzer. As you turn the anvil cap, the anvil is secured against the hemolyzer.

5. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

6. Press **No**.

Menu Code
(from the Main Menu)
1 ***1***

7. Perform a one-point calibration from the Menu screen:

   a. Select **1 Calibration** and press **Enter**.

   b. Select **1 One-point** and press **Enter**.

Semiannual Maintenance

Perform the following procedures every 6 months. The semiannual maintenance described in this section is based on analyzing 30 samples per day. If your laboratory analyzes more than 30 samples per day, perform this maintenance more frequently.

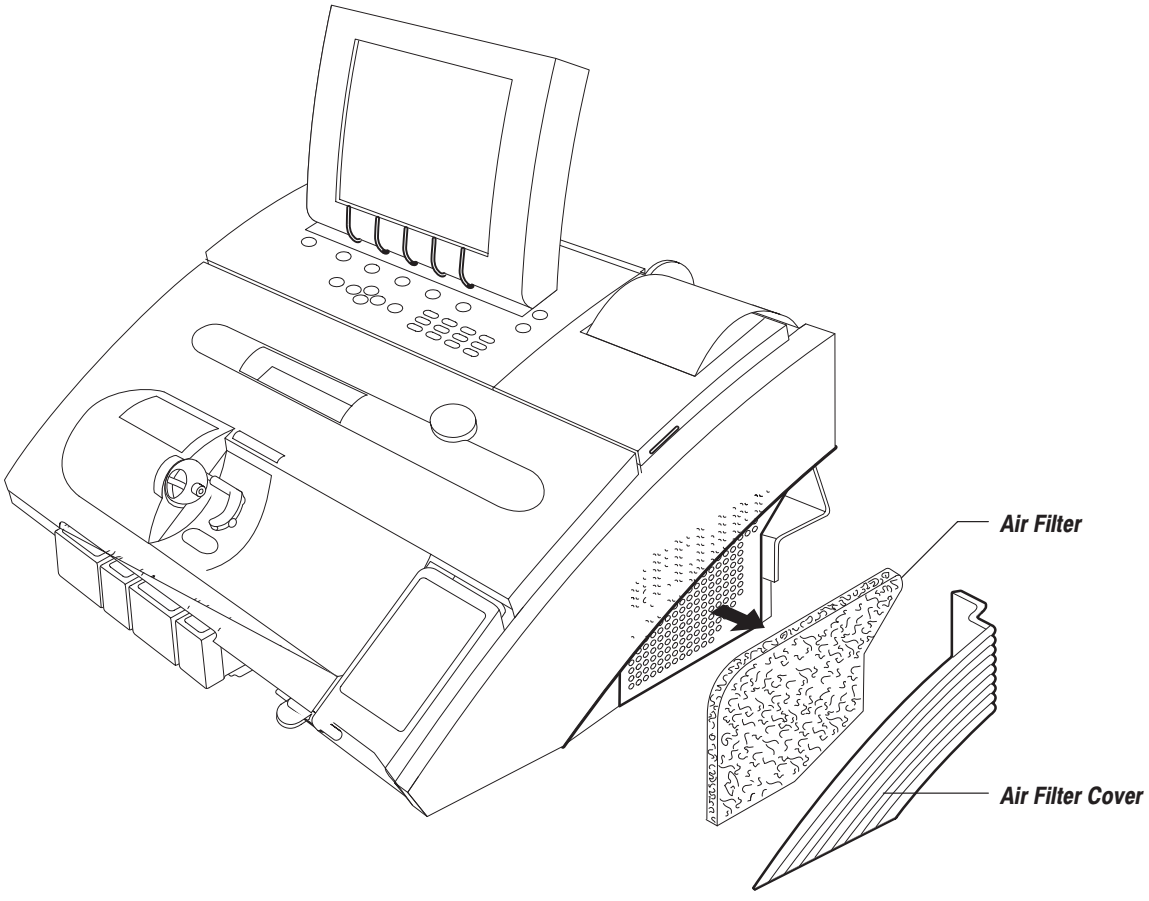
Replacing the Air Filter

Materials required:

- air filter

1. Push the air filter cover down until it snaps out and then pull the cover away from the system as shown in Figure 3-17.

Figure 3-17. Replacing the Air Filter



2. Remove the old air filter and discard it.
3. Press the new air filter into place.

4. Reinstall the air filter cover:
   a. Align the two pins, located inside the air filter cover, underneath the holes.
   b. Push the cover up until it snaps it into place.
5. Press **Home** to return to the Ready screen.

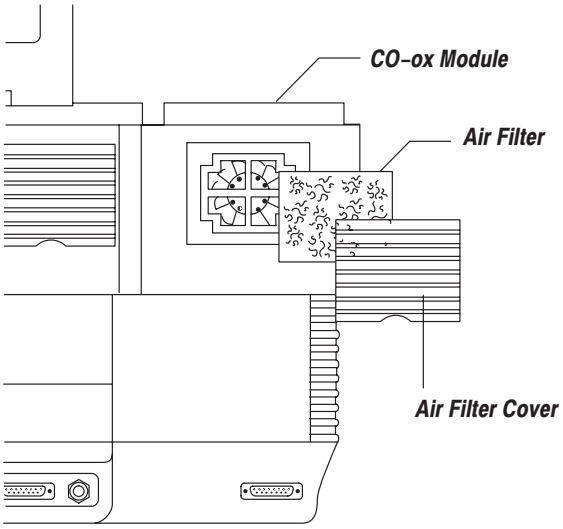
Replacing the CO-ox Air Filter

Materials required:

- CO-ox air filter

1. Push the air filter cover up until it snaps out and then pull the cover away from the system as shown in Figure 3-18.

Figure 3-18. Replacing the CO-ox Air Filter



2. Remove the old air filter and discard it.
3. Press the new air filter into place.
4. Reinstall the air filter cover:
   a. Align the tabs on the cover with the slots in the module.
   b. Push the cover up until it snaps it into place.
5. Press **Home** to return to the Ready screen.

Replacing the Measurement Module Tubing

Materials required:

- measurement module tubing

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

NOTE: If your system has a CO-ox module, follow the procedure described for the appropriate base model. For example, information identified for an 860 also applies to an 865.

1. Cut a piece of measurement module tubing to the appropriate length as shown in Figure 3-19.

Figure 3-19. Measurement Module Tubing Length

System	Tubing Length
840	15.2 cm (6 inches)
850	12 cm (4.75 inches)
860	11.43 cm (4.5 inches)

Menu Code 2 7

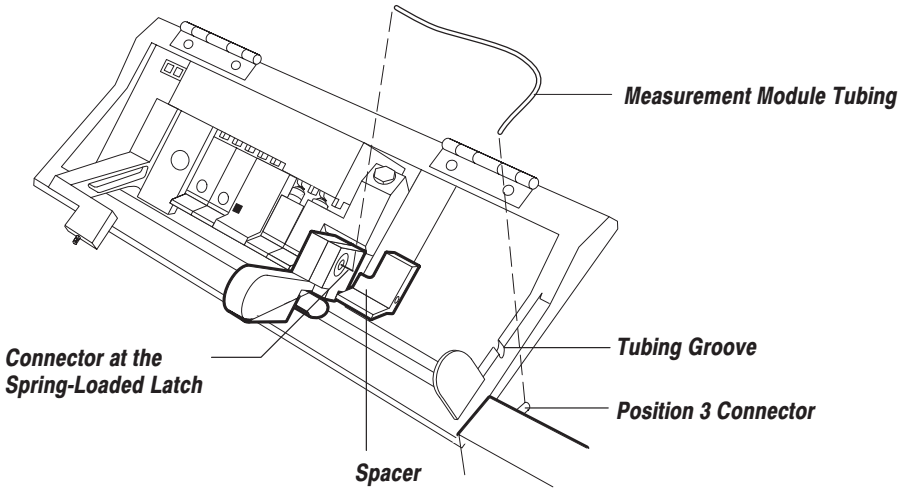
2. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
3. Push up the latches on the measurement module door and lift the door.
4. Take the appropriate action.

If you have an . . .	Then continue with . . .
840	step 5.
850 or 860	step 6.

840

5. Replace the measurement module tubing:
   a. Remove the tubing from the connector at the spring-loaded latch in the measurement block as shown in Figure 3-20.

Figure 3-20. Replacing the Measurement Module Tubing on an 840

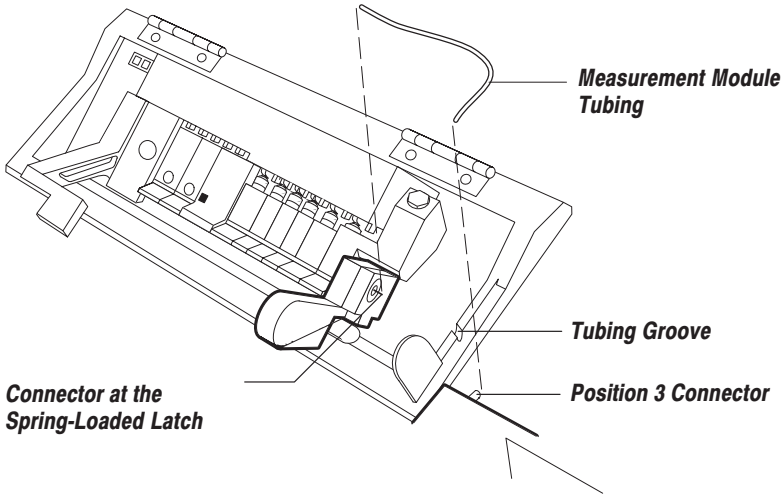


   b. Remove the tubing from the spacer.
   c. Disconnect the tubing from the connector at position 3 on the reagent manifold.
   d. Push the new tubing through the spacer.
   e. Connect the left end of the tubing to the spring-loaded latch.
   f. Connect the right end of the tubing to the connector at position 3.
   g. Press the tubing into the tubing groove.
   h. Continue with step 7.

850 860

6. Replace the measurement module tubing:
   a. Remove the tubing from the connector at the spring-loaded latch in the measurement block as shown Figure 3-21.
   b. Disconnect the tubing from the connector at position 3 on the reagent manifold.
   c. Connect the left end of the new tubing to the spring-loaded latch.
   d. Connect the right end of the tubing to the connector at position 3.
   e. Press the tubing into the tubing groove.

Figure 3-21. Replacing the Measurement Module Tubing



7. Close the measurement module door.
8. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
9. Press **Yes** to perform a two-point calibration.

Replacing the CO-ox Sample Tubing

Materials required:

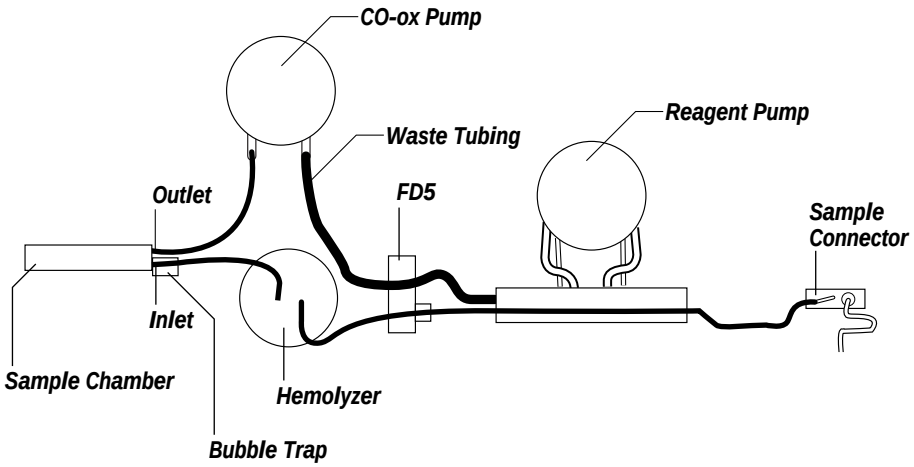
- CO-ox sample tubing

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code
2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Replace the CO-ox sample tubing as shown in Figure 3-22:

Figure 3-22. Replacing the CO-ox Sample Tubing



   a. Remove the anvil cap from the hemolyzer.
   b. Disconnect both pieces of tubing from the anvil.
   c. Remove the tubing guide on FD5 and gently pull the tubing through FD5 toward the sample connector.
   d. Disconnect the CO-ox sample tubing from the sample connector.
   e. Connect the flared end of the replacement tubing to the sample connector.
   f. Press the tubing guide on FD5 into place.
   g. Thread the replacement tubing through FD5.
   h. Connect the replacement tubing to the anvil.
   i. Disconnect both pieces of sample tubing from the sample chamber.
   j. Connect one end of the replacement tubing to the inlet on the sample chamber and the other end to the anvil.
   k. Reinstall the anvil cap on the hemolyzer. Listen for a click, which indicates that the anvil is in place.

l. Disconnect the sample tubing from the CO-ox pump.

m. Connect one end of the replacement tubing to the outlet on the sample chamber and the other end to the CO-ox pump.

3. Replace the waste tubing:

   a. Disconnect the waste tubing from the CO-ox pump.

   b. Disconnect the waste tubing from the inlet on the reagent manifold on the base model.

   c. Gently pull the waste tubing through the hole in the FD5 housing.

   d. Thread the replacement tubing through the hole in the FD5 housing.

   e. Connect the replacement tubing to the inlet on the reagent manifold.

   f. Connect the other end of the replacement tubing to the CO-ox pump.

4. Press **Continue.**

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

5. Press **No**.

Menu Code
(from the Main Menu)
1 ***1***

6. Perform a one-point calibration from the Menu screen:

   a. Select **1 Calibration** and press **Enter**.

   b. Select **1 One-point** and press **Enter**.

Yearly Maintenance

Perform the following procedures every 12 months. These procedures are based on analyzing 30 samples per day. If your laboratory analyzes more than 30 samples per day, perform this maintenance more frequently.

Use this procedure to replace the tubing on the sample pump, the waste pump, the reagent pump, and the CO-ox module pump. The sample pump, waste pump, and CO-ox module pump tubing assemblies each contain one piece of tubing. The reagent pump tubing assembly contains two pieces of tubing.

Replacing the Pump Tubing

NOTE: When you replace pump tubing, replace the tubing for all the pumps. Replacing the tubing on only one or two pumps can affect pump calibration and cause incorrect flow rates.

Materials required:

- sample pump tubing assembly
- waste pump tubing assembly
- reagent pump tubing assembly
- CO-ox pump tubing assembly

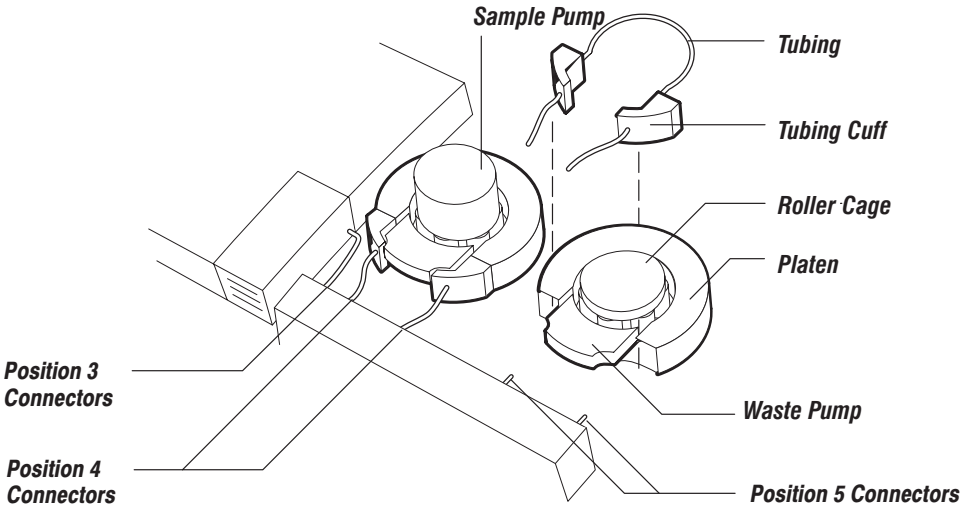
BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards,* for recommended precautions when working with biohazardous materials.

Menu Code

2 ***7***

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Replace the sample pump and waste pump tubing as shown in Figure 3-23. The CO-ox pump has one piece of tubing, which is replaced using the procedure for the sample pump tubing.

Figure 3-23. Replacing the Sample and Waste Pump Tubing

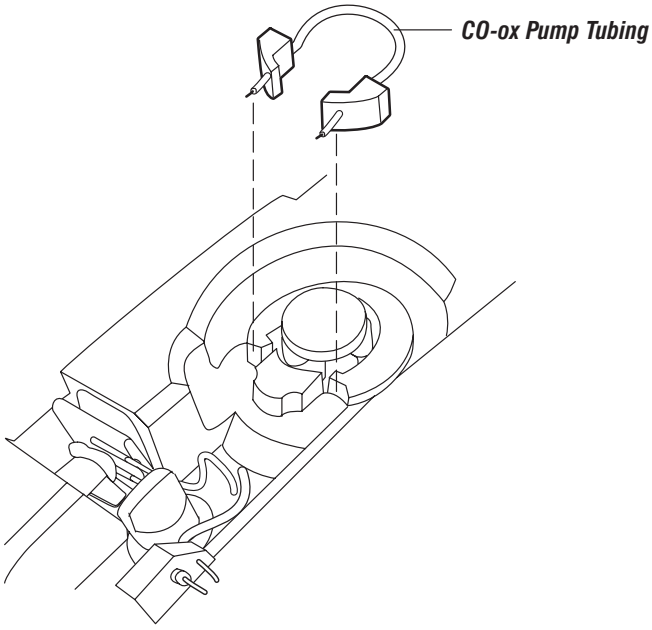


a. Perform the appropriate step.

If you are replacing . . .	*Then disconnect the . . .*
sample pump tubing	tubing from both connectors at position 4 on the reagent manifold.
waste pump tubing	tubing from both connectors at position 5 on the reagent manifold.
CO-ox pump tubing	sample and waste tubing with two-way connectors from the CO-ox pump as shown in Figure 3-24.

3. Replace the reagent pump tubing as shown in Figure 3-23:
   a. Select the replacement tubing that has the tubing collar.
   b. Grasp the left tubing cuff and pull it away from the platen.
   c. While holding the tubing, turn the roller cage clockwise and gently pull the tubing away from the platen and the roller cage.
   d. Discard the tubing according to your laboratory protocol.
   e. Hold the new tubing assembly with the tubing in front.

Figure 3-24. Replacing the CO-ox Pump Tubing



f. Place the left tubing cuff under the left side of the platen.

NOTE: Do not stretch the tubing.

g. Place the tubing around the outside of the rollers.

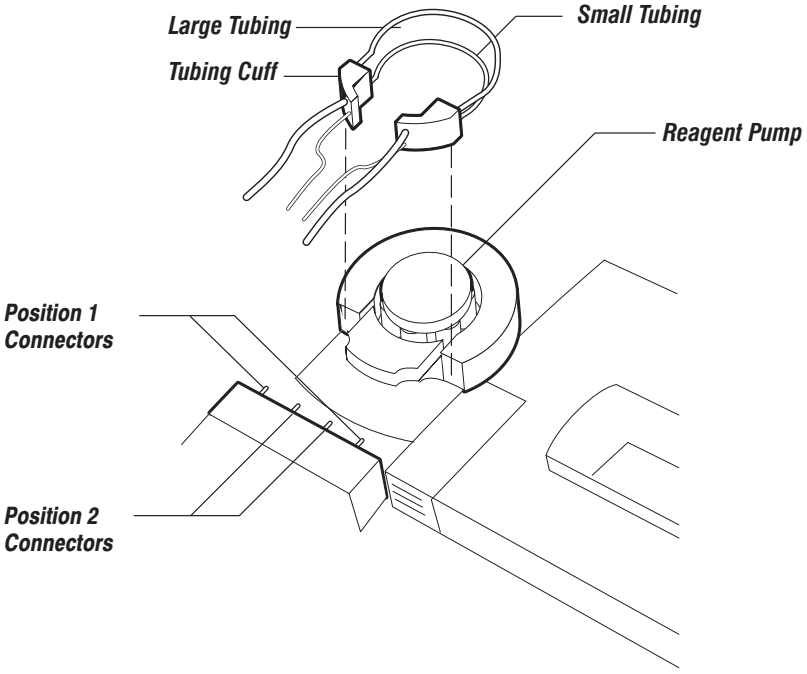
h. Hold the right tubing cuff below the right side of the platen and turn the roller cage clockwise to gently work the new tubing between the platen and roller cage.

i. Place the right tubing cuff under the right side of the platen.

4. Connect the pump tubing.

If you replaced . . .	*Then . . .*
sample pump tubing	connect tubing to both connectors at position 4 on the reagent manifold.
waste pump tubing	connect tubing to both connectors at position 5 on the reagent manifold.
CO-ox pump tubing	connect sample and waste tubing connectors on CO-ox pump tubing.

Figure 3-25. Replacing the Reagent Pump Tubing



a. Disconnect the tubing from the reagent manifold.
b. Grasp the left tubing cuff and pull it away from the platen.
c. While holding the tubing, turn the roller cage clockwise and gently pull the tubing away from the platen and the roller cage.
d. Discard the tubing according to your laboratory protocol.
e. Hold the new tubing assembly with the large tubing in front.
f. Place the left tubing cuff in the groove under the left side of the platen.

NOTE: Do not stretch the tubing.

g. Place the tubing around the outside of the rollers.
h. Hold the right tubing cuff below the right side of the platen and turn the roller cage clockwise to gently work both pieces of the new tubing between the platen and roller cage.
i. Place the right tubing cuff under the right side of the platen.

5. Connect the tubing to the reagent manifold:
   a. Connect the left end of the large tubing to the connector at left position 1.
   b. Connect the right end of the large tubing to the connector at right position 1.
   c. Connect the left end of the small tubing to the connector at left position 2.
   d. Connect the right end of the small tubing to the connector at right position 2.

6. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

7. Press **No**.

Menu Code
(from the Main Menu)
3 ***1*** ***2***

8. Calibrate the reagent pump from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **2 Pump Flow Rate** and press **Enter**.
   d. Press **Calibrate Pump**.
   e. Press **Exit Test** when the Pump calibration complete message appears.

Menu Code
(from the Main Menu)
1 ***2***

9. Perform a two-point calibration from the Menu screen:
   a. Select **1 Calibration** and press **Enter**.
   b. Select **2 Two-point** and press **Enter**.

Replacing the Reagent Manifold Vent Filter

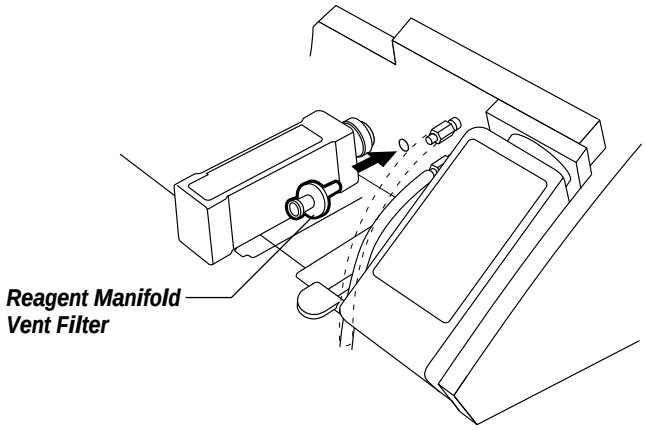
Perform the following procedure annually. This schedule is based on analyzing 30 samples per day. If your laboratory analyzes more than 30 samples per day, perform this maintenance more frequently.

Materials required:

- reagent manifold vent filter

1. Remove the old reagent manifold vent filter from the reagent manifold vent inlet and discard it.
2. Insert the new filter into the reagent manifold vent inlet as shown in Figure 3-26.

Figure 3-26. Replacing the Reagent Manifold Vent Filter



3. Press **Home** to return to the Ready screen.

As-Required Procedures

Emptying the Waste Bottle

Materials required:

- 10% solution of household bleach

NOTE: Dilute household bleach (5.25% sodium hypochlorite) 1:10 with reagent-quality water.

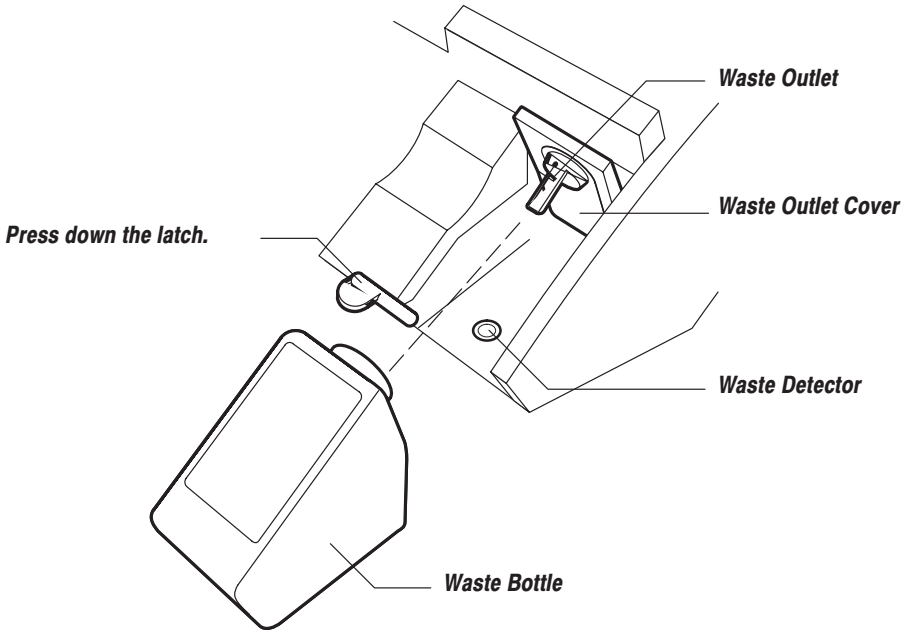
- reagent water
- lint-free tissue or swabs

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards,* for recommended precautions when working with biohazardous materials.

WARNING Wear safety glasses, gloves, and a laboratory coat when performing this procedure.

1. Press and hold down the waste bottle latch while removing the waste bottle from the compartment, as shown in Figure 3-27.

Figure 3-27. Removing the Waste Bottle

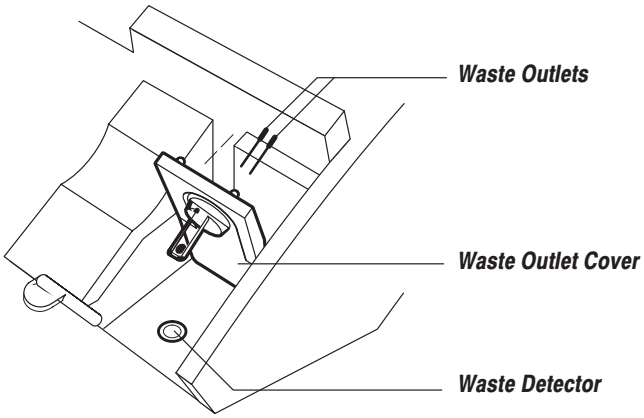


2. Cover the waste bottle with the attached cap to avoid spills when transporting the bottle.

NOTE: The waste bottle is disposable and can be autoclaved before you discard it. The waste bottle is not reusable after autoclaving. Cover the waste bottle with the cap provided and discard the bottle according to your laboratory protocol or infection control policy.

3. Discard the waste bottle contents according to your laboratory biohazard protocol.
4. Clean the waste outlets:
   a. Wipe the waste outlet cover with a lint-free tissue dampened with a 10% solution of household bleach.
   b. Rinse with reagent water.
5. If required, remove the waste outlet cover and clean the waste outlets as shown in Figure 3-28:
   a. Grasp the waste outlet cover and pull it off.
   b. Wipe the outlets with a lint-free tissue dampened with a 10% solution of household bleach.
   c. Clean the waste outlet cover with the bleach solution.
   d. Rinse the waste outlets and the waste outlet cover with reagent water.

Figure 3-28. Removing the Waste Outlet Cover



6. Reinstall the waste outlet cover:
   a. Press the alignment pins on the bottom of the waste outlet cover into the system holes.
   b. Align the alignment pins on the top of the waste outlet cover with the system holes, and then align the waste outlets with the holes in the cover.
   c. Press the cover firmly into place, leaving no gaps
7. Reinstall the waste bottle, ensuring that the latch slides back in place.
8. Ensure that the waste outlet cover fits tightly into the waste bottle opening.

Cleaning the Reference Sensor and Removing Bubbles

Use this procedure to clean the reference sensor and to remove bubbles at the electrode tip and in the passage between the electrode compartment and the KCl reservoir.

Materials required:

- reagent water
- lint-free swab

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards,* for recommended precautions when working with biohazardous materials.

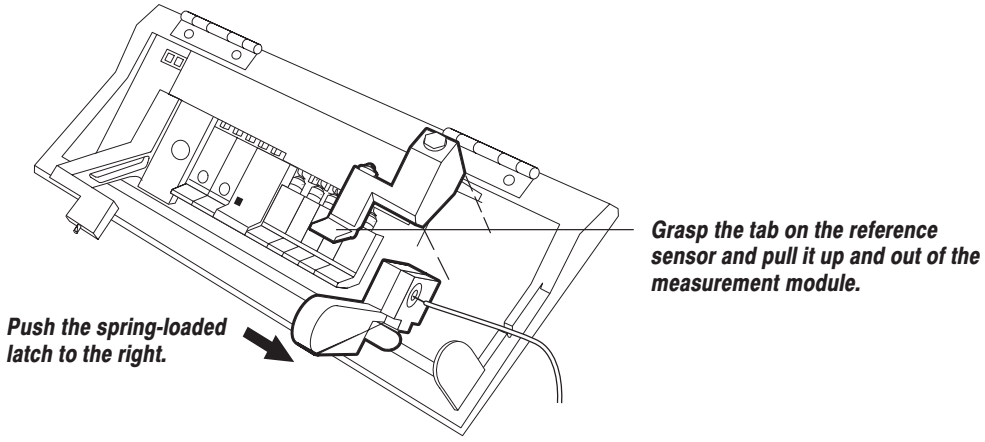
Menu Code
2 ***7***

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Push up the latches on the measurement module door and lift the door.
3. Push the spring-loaded latch to the right as shown in Figure 3-29.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

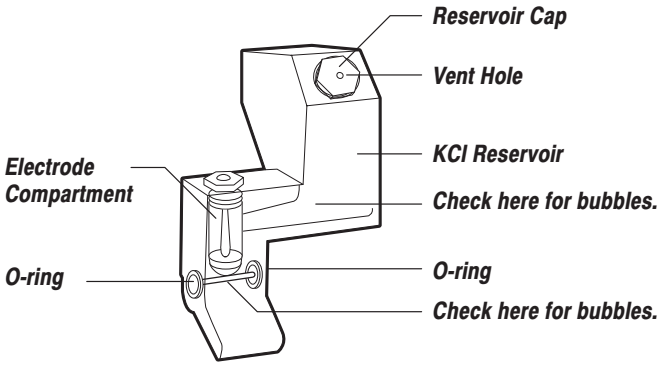
4. Grasp the tab on the reference sensor and pull the sensor up and out of the measurement module.

Figure 3-29. Removing the Reference Sensor from the Measurement Module



5. Check the sensor for bubbles at the electrode tip and between the electrode compartment and the KCl reservoir as shown in Figure 3-30.

Figure 3-30. Checking the Reference Sensor for Bubbles



6. Tap the front face of the sensor with your knuckle to release any bubbles.
7. Clean any salt deposits on the reference sensor with a lint-free swab moistened with deionized water and dry it thoroughly.
8. Ensure that the O-rings are in place on both sides of the sensor.
9. Clean the O-ring area on the spring-loaded latch with a lint-free swab moistened with reagent water.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

10. Reinstall the sensor:
    a. Gently align the top of the reference sensor with the sensor contact.
    b. Snap the sensor down into place.
    c. Press the tab on the spring-loaded latch to release the latch.
11. Close the measurement module door.
12. Press **Continue**.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
13. Allow the system to warm for up at least 15 minutes.
14. When the temperature is stable, press **Yes** to perform a two-point calibration.

Procedural Notes

After the sensor temperature equilibrates, remove the sensor and inspect for bubbles. As the temperature of the sensor rises to 37°C, gas is driven from the solution, causing bubbles. Remove any bubbles present.

Cleaning the Sample Ground/Temperature Sensor

Materials required:

- 0.022 inch diameter clot-removal line (to fit through a 0.030 inch ID pathway)

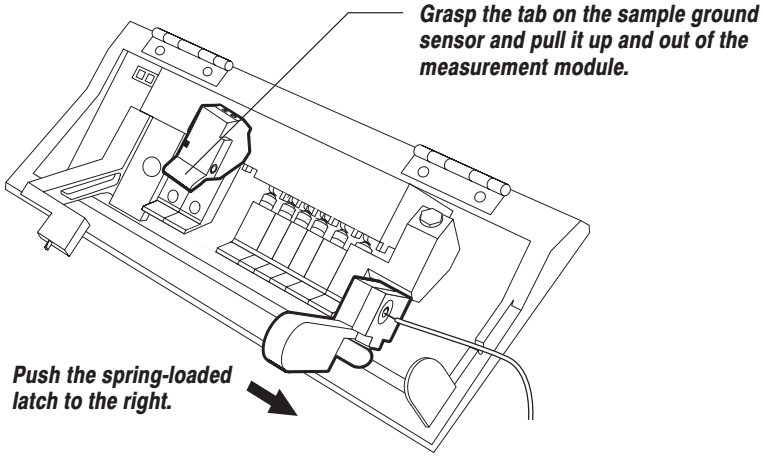
Menu Code
2 ***7***

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Push up the latches on the measurement module door and lift the door.
3. Push the spring-loaded latch to the right as shown in Figure 3-31.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

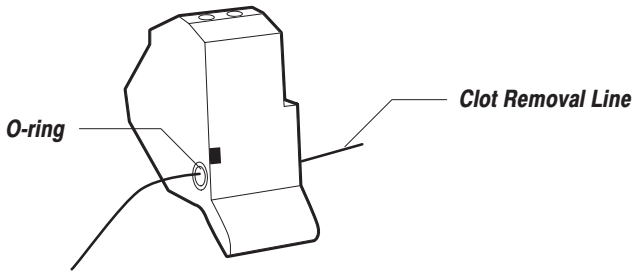
4. Grasp the tab on the sample ground/temperature sensor and pull the sensor up and out of the measurement module.

Figure 3-31. Removing the Sample Ground/Temperature Sensor from an 850



5. Push a clot removal line through the sensor to clear away any obstructions as shown in Figure 3-32.

Figure 3-32. Cleaning the Sample Ground/Temperature Sensor



6. Ensure that the O-ring is in place. Replace the O-ring if it is worn or damaged.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

NOTE: If the sensor does not insert easily into the measurement module, slide the remaining sensors to the right to create more space.

7. Reinstall the sensor:
   a. Gently align the top of the sensor with the sensor contact.
   b. Snap the body of the sensor down into place.
   c. Press the tab on the spring-loaded latch to release the latch.
8. Close the measurement module door.
9. Press **Continue** .

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
10. Press **No**.
11. Allow the system to warm up for at least 15 minutes.

Menu Code
(from the Main Menu)
3 ***2***

12. Check the sample path temperature from the Menu screen:
    a. Select **3 Troubleshooting** and press **Enter**.
    b. Select **2 Temp/pAtm** and press **Enter**.
    c. Press **Start Test**.
    d. Press **Stop Test**.
    e. Check the screen for the sample path temperature.
    f. If the temperature control system is off, press **Reset Control**.
    g. Press **Exit Test**.

Menu Code
(from the Main Menu)
1 ***2***

13. Perform a two-point calibration from the Menu screen:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **2 Two-point** and press **Enter**.

Cleaning the Roller Cages

Use this procedure to clean the roller cages for the reagent, sample, or waste pumps.

Materials required:

- 10% solution of household bleach

NOTE: Dilute household bleach (5.25% sodium hypochlorite) 1:10 with reagent-quality water.

- reagent water
- lint-free tissue and swabs

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards,* for recommended precautions when working with biohazardous materials.

Menu Code

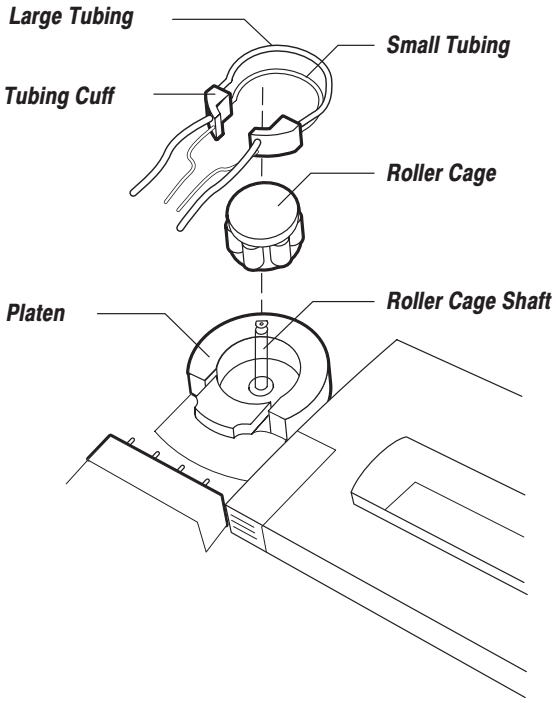
2 ***7***

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Disconnect the pump tubing from the reagent manifold.

NOTE: Do not stretch the tubing.

3. While holding the left side of the tubing, turn the roller cage clockwise and gently pull the tubing away from the platen and the roller cage.
4. Set the tubing assembly aside.
5. Grasp the roller cage and gently pull it straight off its shaft as shown in Figure 3-33.

Figure 3-33. Removing a Roller Cage



WARNING Wear safety glasses, gloves, and a laboratory coat when handling bleach.

6. Clean the roller cage:
   a. Clean the rollers with a lint-free tissue moistened with a 10% solution of household bleach.
   b. Clean the interior surface of the roller cage with a lint-free swab moistened with the bleach solution.
   c. Clean the roller cage shaft with a lint-free tissue moistened with the bleach solution.
   d. Rinse the rollers, the cage, and the shaft with reagent water.
   e. Dry the roller cage thoroughly.
   f. Ensure that the rollers turn freely.
7. Reinstall the roller cage:
   a. Replace the roller cage on the shaft.
   b. Turn the roller cage on the shaft until it stops.
   c. Press the roller cage down until the cage snaps into place.
8. Connect the tubing as described in *Replacing the Pump Tubing*, page 3-39.

9. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

10. Press **Yes** to perform a two-point calibration.

Cleaning the Reagent Fittings

Materials required:

- 10% solution of household bleach

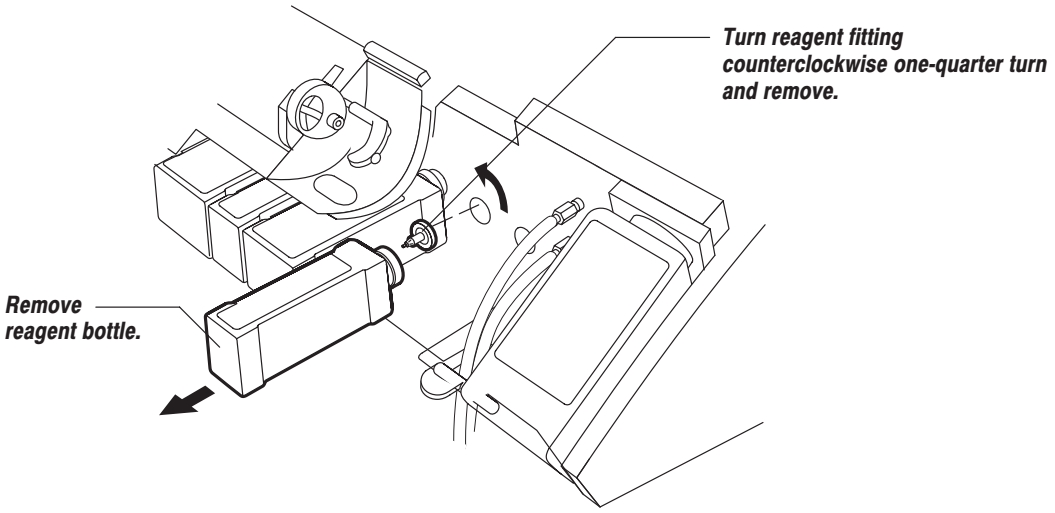
NOTE: Dilute household bleach (5.25% sodium hypochlorite) 1:10 with reagent quality water.

- reagent water
- lint-free swabs

Menu Code
2 ***7***

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Remove the required reagent bottle as shown in Figure 3-34.
3. Grasp the reagent fitting and turn it counterclockwise one-quarter turn.
4. Pull the fitting straight out.

Figure 3-34. Removing a Reagent Fitting on an 850



5. Replace the fitting if it is deformed, and then continue with step 8.

WARNING Wear safety glasses, gloves, and a laboratory coat when handling bleach.

6. Clean the fitting with a swab moistened with a 10% solution of household bleach.
7. Rinse the fitting with reagent water and dry thoroughly.

   Ensure that the O-ring is in place on the back of the reagent fitting.
8. Reinstall the fitting into the appropriate position on the reagent manifold, and turn clockwise one-quarter turn.

   Ensure that the fitting fits tightly into the reagent manifold.
9. Reinstall the reagent bottle.

   Push the bottle to ensure that it fits tightly on the reagent fitting.
10. Repeat steps 2 through 9 to remove and clean other reagent fittings as required.
11. Press **Continue**.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
12. Press **No**.

Menu Code
3

13. Perform a prime sequence:
    a. Select **3 Prime** and press **Enter**.
    b. Select the appropriate reagents to prime and press **Enter**.
    c. Press **Done**.
    d. Press **Home** or **Menu** when the Prime menu appears.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
14. Take the appropriate action.

If . . .	***Then . . .***
you want to perform a two-point calibration	press **Yes**.
you do not want to perform a two-point calibration	a. Press **No**. b. Press **Home** to return to the Ready screen.

Cleaning the Sample Port

Materials required:

- 10% solution of household bleach

NOTE: Dilute household bleach (5.25% sodium hypochlorite) 1:10 with reagent quality water.

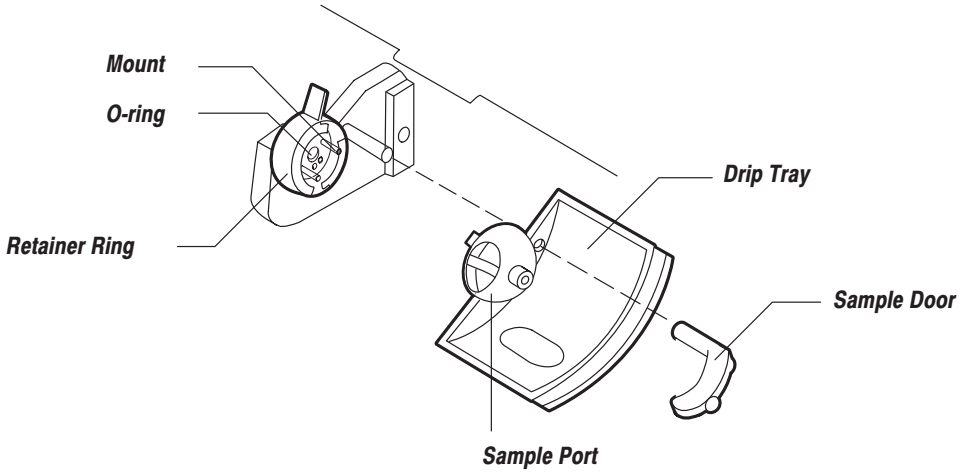
- reagent water
- lint-free swabs

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code
2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Pull off the sample door as shown in Figure 3-35.

Figure 3-35. Removing the Sample Port



3. Grasp the tab on the retainer ring and firmly pull the tab toward you to rotate the ring.
4. Grasp the sample port and attached drip tray and pull it off the mount as shown in Figure 3-35.

WARNING Wear safety glasses, gloves, and a laboratory coat when handling bleach.

5. Clean any deposits on the sample port, the drip tray, and the mount with a lint-free swab moistened with a 10% solution of household bleach.
6. Rinse the sample port and drip tray and the mount with reagent water.

NOTE: Ensure that the three O-rings are in place.

7. Reinstall the sample port, matching the tab on the sample port to the notch in the retainer ring.
8. Push the tab on the retainer ring away from you until it locks in place.
9. Reinstall the sample door, ensuring that it snaps in place.
10. Press **Continue**.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
11. Press **Yes** to perform a two-point calibration.

Cleaning the Roll Printer

Materials required:

- alcohol
- standard copier paper

WARNING Wear gloves to protect your hands from the alcohol.

1. Remove the paper roll from the roll printer:
   a. Pull the paper spool up and remove the paper from the spool.
   b. Lift the printer lever and remove the paper from the printer.
   c. Remove the paper roll and set it aside.
2. Cut a piece of standard copier paper in half lengthwise to make a strip of paper 10.8 cm (4.25 inches) wide.
3. Moisten the center of the paper along its width with the alcohol. Leave the two ends of the paper dry.

Menu Code
7 ***3***

4. Shut down the system from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **3 Shutdown** and press **Enter**.
   c. Press **Yes**.

CAUTION: You must wait at least 1 minute before you disconnect the power cord, and then wait at least 10 seconds before you reconnect the power cord. If you do not adhere to the time intervals, you can damage the system.

5. Wait at least 1 minute, and then disconnect the power cord from the power supply.
6. Insert the paper into the printer, and push the paper through the printer until the moistened part of the paper is past the print head.
7. Pull the paper back and forth several times past the printer head.

8. Remove the paper from the printer.
9. Reconnect the power cord to the power supply and allow the system to warm up.
10. Reinstall the printer paper as described in *Replacing the Printer Paper*, page 3-66.
11. Verify the printing quality as described in *Roll Printer Test* in Section 4.

Cleaning the Sample Path with Glutaraldehyde

Materials required:

- glutaraldehyde
- aspiration adapter
- lint-free tissue or swabs
- test/blank reference sensor (TB5)

860
- test/blank glucose sensor (TB4)

860
- test/blank lactate sensor (TB4)

Bayer Diagnostics recommends using Cidex™, a 2% activated glutaraldehyde solution, to discourage microbial growth in the sample path.

CAUTION: Do not use alcohol to perform this procedure. Alcohol can damage the sensors.

WARNING When handling glutaraldehyde, follow appropriate chemical safety guidelines, which include wearing safety glasses, gloves, and laboratory coat.

1. Prepare the glutaraldehyde solution according to the manufacturer's instructions.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

2. Take the appropriate action.

If you have an . . .	*Then . . .*
840 or 850	go to step 3.
860	a. Remove the glucose and lactate biosensors. b. Install the test/blank sensors. c. Go to step 3.

Menu Code
2 ***1***

3. Deproteinize the sample path:
   a. Prepare the deproteinizer as directed on the package.
   b. Select **2 Maintenance** and press **Enter**.
   c. Select **1 Deproteinize** and press **Enter**.
   d. Invert the deproteinizer vial several times to mix.
   e. Insert an aspiration adapter into the sample port and insert the other end into the deproteinizer.
   f. Press **Analyze**.
   g. When prompted, remove the adapter.
   h. Wait for the deproteinizing cycle to finish.

      A message box appears prompting you to condition the sensors.

4. Perform the cleaning cycle:
   a. Press **Yes**.
   b. Insert an aspiration adapter into the sample port and immerse the other end in the glutaraldehyde solution.
   c. Press **Analyze**.
   d. When prompted, remove the adapter.
   e. Wait 5 minutes for the cleaning cycle to finish.

   NOTE: Press **Cancel** if you want to stop cleaning.

   The cleaning cycle finishes. The system performs an extended wash sequence. The Calibrate System message box appears at the end of the wash sequence.

5. Press **No**.

Menu Code
(from the Main Menu)
2 ***8***

6. Initiate a wash sequence from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **8 Wash** and press **Enter**.

   NOTE: As you install the biosensors, ensure that the biosensors are in the correct location. Visually verify that you align the contacts on the biosensors with the contacts in the measurement module.

   ⚠ **CAUTION:** Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

7. When the wash sequence finishes, remove the test/blank glucose and lactate sensors and reinstall the biosensors as described in *Replacing the Glucose and Lactate Biosensors* page 3-86.

Menu Code
(from the Main Menu)
1 2

8. Perform a two-point calibration from the Menu screen:

   NOTE: Glutaraldehyde may cause excessive drift to the K^+ and Ca^{++} sensors. Repeat calibrations until the system performs a successful calibration.

   a. Select **1 Calibration** and press **Enter**.

   b. Select **2 Two-point** and press **Enter**.

9. Analyze a minimum of two levels of quality control material to verify sensor performance.

10. Empty and clean the waste bottle, waste outlets, and waste outlet cover as described in *Emptying the Waste Bottle*, page 3-45.

Cleaning the Sample Path with Bleach

Materials required:

- 10% solution of household bleach

NOTE: Dilute household bleach (5.25% sodium hypochlorite) 1:10 with reagent-quality water.

- aspiration adapter
- lint-free tissue or swabs
- test/blank reference sensor (TB5)
- test/blank glucose sensor (TB4) (860)
- test/blank lactate sensor (TB4) (860)

NOTE: If your system has a CO-ox module, follow the procedure described for the appropriate base model. For example, information identified for an 860 also applies to an 865.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

860

CAUTION: Do not expose the glucose and lactate biosensors to deproteinizer or bleach. Replace the biosensors with test/blank sensors (TB4) before cleaning the sample path. Reinstall the biosensors within 2 hours.

1. Take the appropriate action.

If you have an . . .	*Then . . .*
840 or 850	go to step 2.
860	a. Remove the glucose and lactate biosensors. b. Install the test/blank glucose and lactate sensors (TB4). c. Go to step 2.

CAUTION: Do not expose the reference sensor to bleach. Replace the reference sensor with the test/blank reference sensor (TB5). Do not substitute a new reference sensor.

2. Replace the reference sensor with a test/blank reference sensor:
   a. Remove the reference sensor from the measurement module and set it aside.
   b. Install a test/blank reference sensor (TB5) in the measurement module.

Menu Code 2 1

3. Deproteinize the sample path:
   a. Prepare the deproteinizer as directed on the package.
   b. Select **2 Maintenance** and press **Enter**.
   c. Select **1 Deproteinize** and press **Enter**.
   d. Invert the deproteinizer vial several times to mix.
   e. Insert an aspiration adapter into the sample port and insert the other end into the deproteinizer.
   f. Press **Analyze**.
   g. Remove the adapter when prompted.
   h. Wait 5 minutes for the deproteinizing cycle to finish.

   A message box appears prompting you to condition the sensors.

WARNING afety glasses, gloves, and a laboratory coat when handling bleach.

4. Perform the cleaning cycle:
   a. Press **Yes**.
   b. Insert an aspiration adapter into the sample port and immerse the other end in the 10% bleach solution.
   c. Press **Analyze**.
   d. When prompted, remove the adapter.
   e. Wait 5 minutes for the cleaning cycle to finish.

   NOTE: Press **Cancel** if you want to stop cleaning.

   When the cycle finishes, the system performs an extended wash sequence. The Calibrate System message box appears at the end of the wash sequence.
5. Press **No**.

Menu Code
(from the Main Menu)
2 ***8***

6. Initiate a wash sequence from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **8 Wash** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

860

NOTE: As you install the sensors, ensure that the sensors are in the correct location. Visually verify that you align the contacts on the sensors with the contacts in the measurement module.

860

7. When the wash sequence finishes, remove the test/blank glucose and lactate sensors (TB4) and reinstall the glucose and lactate biosensors as described in *Replacing the Glucose and Lactate Biosensors*, page 3-86.
8. Remove the test/blank reference sensor (TB5) and reinstall the reference sensor as described in *Replacing the Reference Sensor*, page 3-71.
9. Empty and clean the waste bottle, waste outlets, and waste outlet cover as described in *Emptying the Waste Bottle*, page 3-45.

Menu Code
(from the Main Menu)
1 ***2***

10. Perform a two-point calibration:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **2 Two-point** and press **Enter**.
11. Analyze a minimum of two levels of quality control material to verify sensor performance.

Performing the Automatic Clean Sequence

Use this procedure to manually initiate the cleaning sequence. The system automatically initiates the cleaning sequence every 24 hours at 02:00.

Menu Code
2 ***6***

1. Access Auto Clean from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **6 Auto Clean** and press **Enter**.

   NOTE: To interrupt the Auto Clean sequence at any time, press **Cancel**.

   The Auto Clean sequence takes 10 minutes. A message box appears prompting you to perform a two-point calibration.
2. Press **Yes** to perform a two-point calibration.

Performing a Wash

Menu Code
2 ***8***

1. Access wash from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **8 Wash** and press **Enter**.
2. Press **Home** to return to the Ready screen.

Priming the System

Menu Code
2 ***3***

1. Access the Prime screen from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **3 Prime** and press **Enter**.
2. Select the appropriate reagent to prime and press **Enter**.
3. Press **Done**.
4. Press **Home** or **Menu** when the Prime menu appears.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
5. Take the appropriate action.

If . . .	***Then . . .***
you want to perform a two-point calibration	press **Yes**.
you do not want to initiate a two-point calibration	press **No**. press **Home** to return to the Ready screen.

Stopping the System

Use this procedure to stop the system when you perform maintenance activities such as replacing components. Stopping the system discontinues all fluidic activities such as calibrations and sample analyses.

CAUTION: Because no fluids reach the sensors while the system is stopped, stopping the system for a prolonged period of time may affect the performance of the sensors.

Menu Code

2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Perform the required maintenance task.
3. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
4. Take the appropriate action.

If . . .	*Then . . .*
you want to perform a two-point calibration	press **Yes**.
you do not want to initiate a two-point calibration	a. Press **No**. b. Press **Home** to return to the Ready screen.

Procedural Notes

If calibrations were scheduled while the system was stopped, the system performs the calibrations when you exit the stopped mode.

Reviewing and Printing Workload Statistics

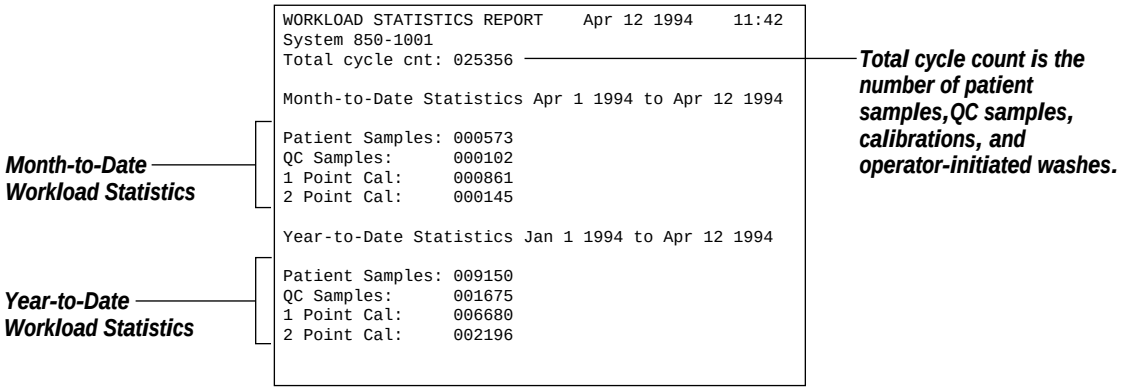
The 800 system collects workload data and provides month-to-date and year-to-date workload statistics reports. The workload statistics report includes the total cycle count of all patient samples, calibrations, and QC samples performed by the system. The yearly statistics are reset every January 1 after the system performs the first sample analysis or calibration. The system automatically prints a workload statistics report.

Menu Code

4 ***6***

1. Access the Workload Stats screen from the Menu screen:
   a. Select **4 Data Recall** and press **Enter**.
   b. Select **6 Workload Stats** and press **Enter**.
2. Press **Print Statistics** to print a workload statistics report.
   The workload statistics report is shown in Figure 3-36.

Figure 3-36. Workload Statistics Report



3. Press **Done** to return to the Menu screen.
4. Press **Home** to return to the Ready screen.

Replacing System Components

Replacing the Reagent Bottles

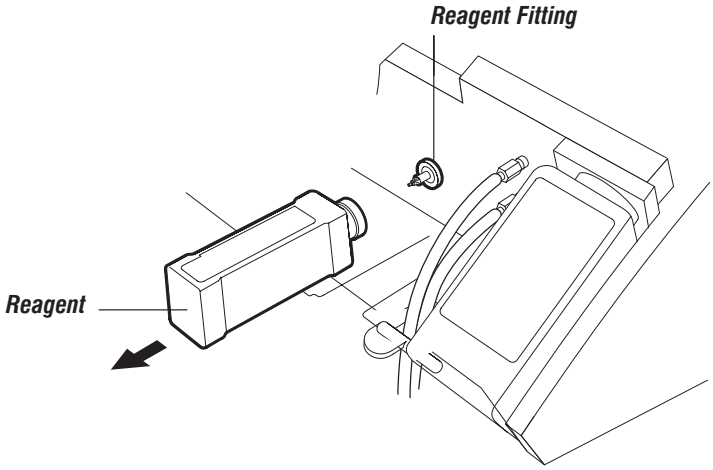
WARNING Wear safety glasses, gloves, and a laboratory coat when handling the reagents.

1. At the Ready screen, press **Enter**.

   The Reagent Levels screen appears.

2. Remove the reagent bottle from the reagent manifold, as shown in Figure 3-37.

Figure 3-37. Removing a Reagent Bottle



3. Write the date installed in the space provided on the new bottle.

NOTE: Do not remove or tighten the cap that contains the reagent septum. Removing the cap damages the integrity of the reagent septum.

4. Remove the plug from the cap of the new reagent bottle.
5. Insert the new reagent bottle into position on the reagent manifold.
6. Push the bottle to ensure that it fits firmly on the reagent fitting.
7. Press **Reset Levels**.

   The Reset Levels screen appears.

8. Select the reagent(s) that you replaced and press **Done**.

   A prime sequence starts followed by a wash sequence. When the wash sequence finishes, the Ready screen appears.

9. Perform a two-point calibration.
   a. Press **Calibrate**.
   b. Select **Two-point** and press **Enter**.
   c. Press **Start Calibration**.

Procedural Notes

Perform two-point calibrations after changing the calibration reagents to ensure that the reagents are acceptable and the system is functioning properly. You can analyze quality control materials with the new reagents and compare the results with the previous QC results after the system is recalibrated.

Replacing the Printer Paper

CAUTION: Do not attempt to print without paper installed or with a double thickness of paper in the printer. Use the paper advance key to feed the paper through the printer.

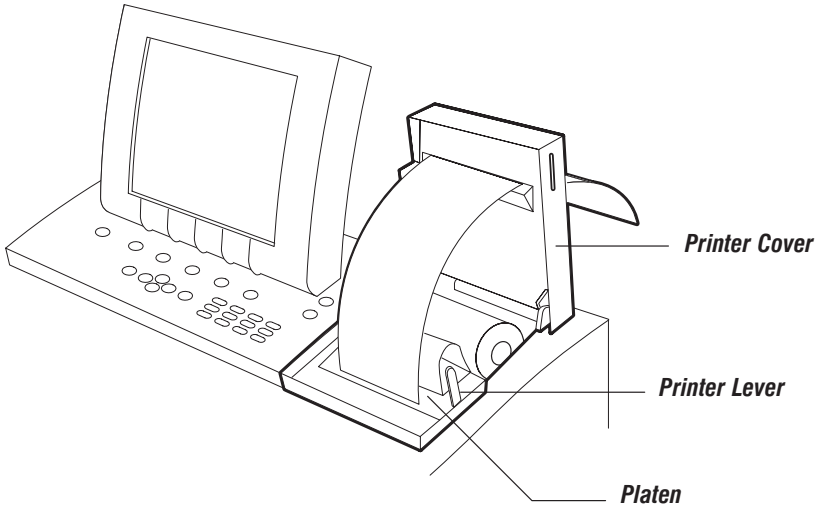
Menu Code
2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Pull up the paper spool.
3. Firmly grasp the old roll of paper and pull it off the spool.

NOTE: Grasp the roll of paper tightly to slide the paper completely off the spool.

4. Reinstall the paper spool.
5. Lift the printer cover.
6. Push up the printer lever.
7. Install a roll of printer paper:
   a. Unroll a small amount of paper from the new roll and cut or fold a clean straight edge, if necessary.
   b. Place the paper roll in the cavity with the paper unrolling from the bottom as shown in Figure 3-38.

Figure 3-38. Installing the Printer Paper Around the Platen



c. Push the paper under the platen until it comes out the front side.

d. Pull the paper from under the platen and push it through the slot in the printer cover.

e. Push down the printer lever.

⚠ **CAUTION:** Pull up the paper firmly as you close the cover to ensure that the paper does not jam under the cover.

f. Close the printer cover.

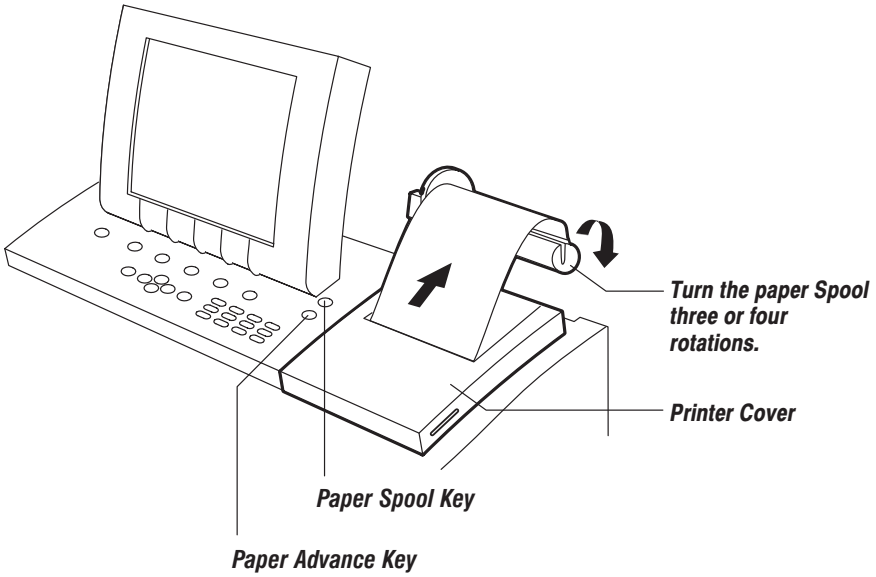
g. Press the paper advance key to ensure the paper moves smoothly and to remove the no paper message.

8. Install the printer paper on the paper spool:

   a. Pull up the paper spool as shown in Figure 3-39.

NOTE: Gently guide the paper against the left edge of the spool when you wind paper on the spool. If the right edge of the paper roll is uneven, the paper can jam.

Figure 3-39. Installing the Printer Paper on the Spool



b. Insert the paper into the paper slot on the spool and turn the spool three or four rotations away from you.

   You can fold the end of the paper 1.3 cm (0.5 inch) and place it into the slot. Press the paper advance key if there is not enough paper.

c. Lower the paper spool until it snaps into place.

9. Press **Continue**.

   A wash sequence starts. When the wash finishes, a message box appears prompting you to perform a two-point calibration.

10. Press **No**.

Procedural Notes

Press the paper advance key to remove the No Paper in Printer message from the status area.

Filling the Reference Sensor

Materials required:

- reference electrode refill
- hex tool
- lint-free tissue

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

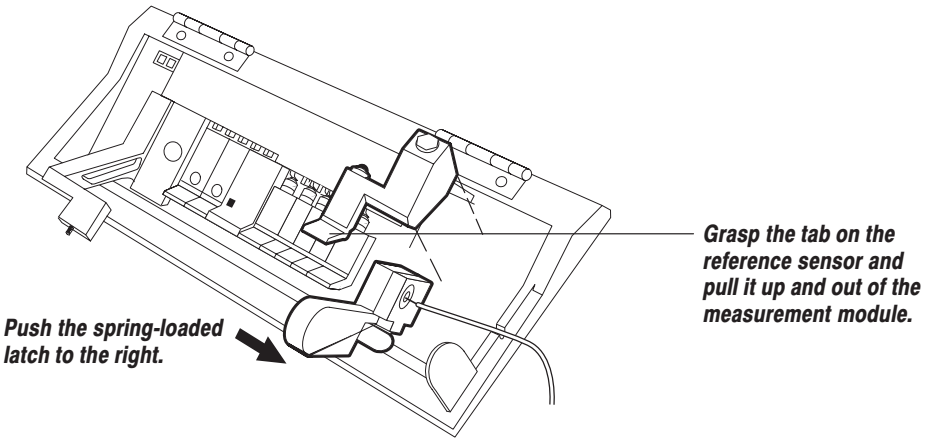
Menu Code
2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

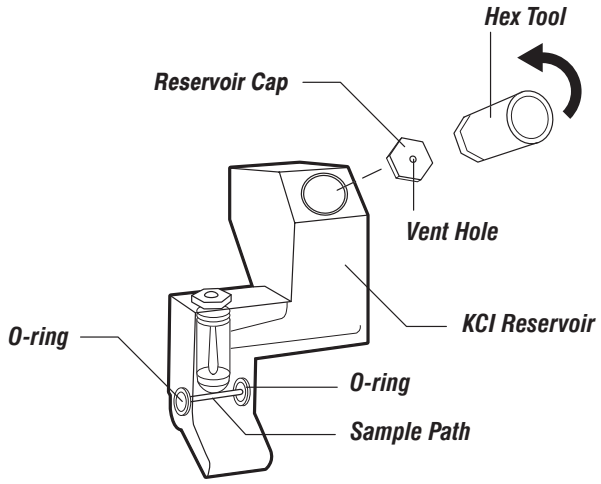
2. Remove the reference sensor as shown in Figure 3-40:
   a. Push up the latches on the measurement module door and lift the door.
   b. Push the spring-loaded latch to the right.
   c. Grasp the tab on the reference sensor and pull the sensor up and out of the measurement module.

Figure 3-40. Removing the Reference Sensor from an 850



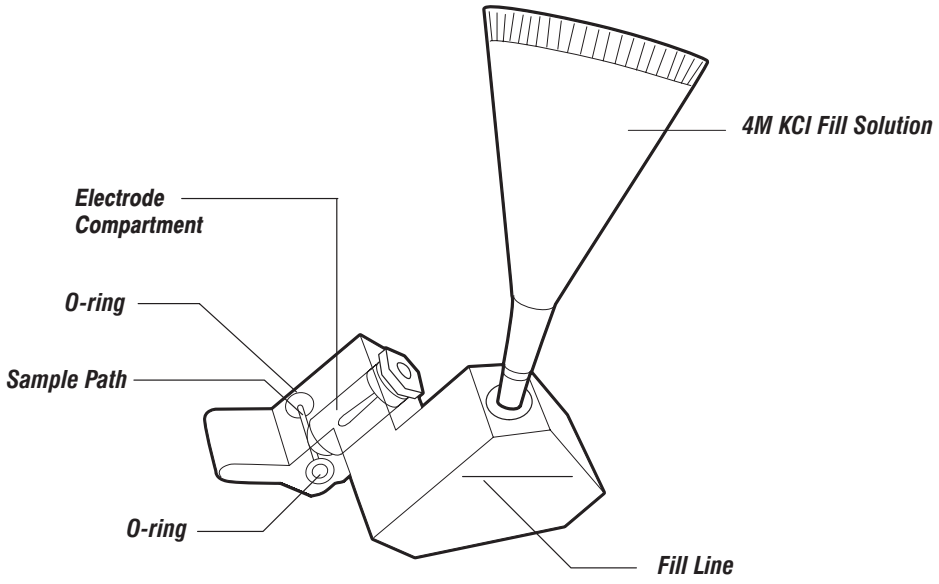
3. Remove the reservoir cap from the reference sensor with the hex tool and set the cap aside as shown in Figure 3-41.

Figure 3-41. Removing the Reservoir Cap with the Hex Tool



4. Add KCl fill solution to the KCl reservoir to the fill line, as shown in Figure 3-42.

Figure 3-42. Filling the Reference Sensor



CAUTION: Do not overtighten the reservoir cap. Overtightening can deform the gasket and cause leaks.

5. Reinstall the reservoir cap and hand-tighten.
6. Continue with *Reinstalling a Sensor*, page 3-89.

Replacing the Reference Sensor

Materials required:

- reference sensor replacement kit
- hex tool
- lint-free tissue

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

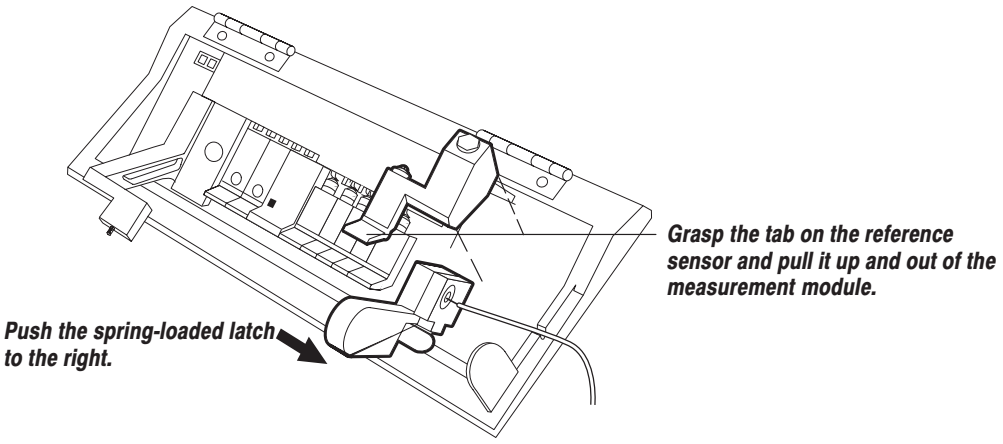
Menu Code
2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

2. Remove the reference sensor as shown in Figure 3-43:
   a. Push up the latches on the measurement module door and lift the door.
   b. Push the spring-loaded latch to the right.
   c. Grasp the tab on the reference sensor and pull the sensor up and out of the measurement module.
   d. Discard the reference sensor according to your laboratory protocol.

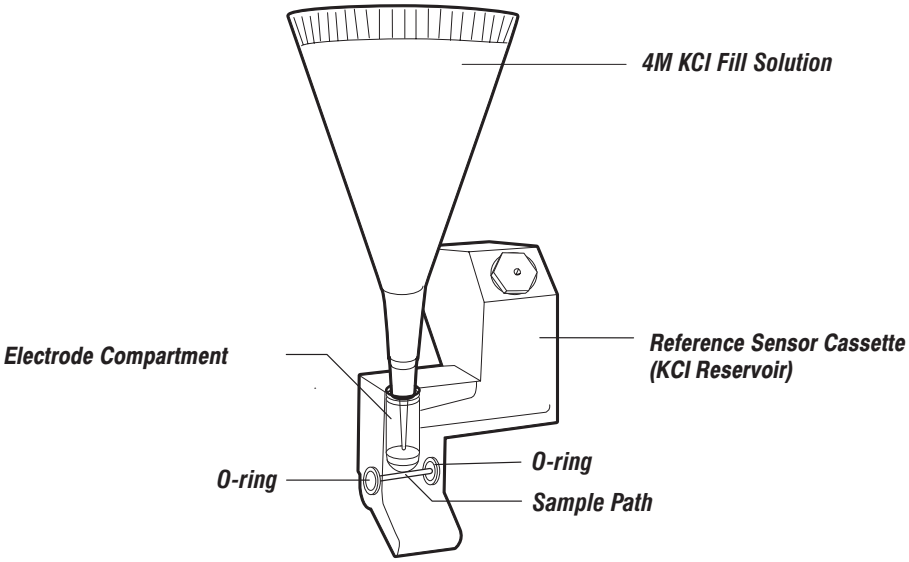
Figure 3-43. Removing the Reference Sensor from an 850



3. Fill the electrode compartment in the new reference sensor:
   a. Remove the reference sensor cassette (KCl reservoir) from its box.
   b. Insert the tip of the KCl fill solution container into the electrode compartment as shown in Figure 3-44.

c. Slowly fill the electrode compartment by gently squeezing the container until the KCl fill solution enters the KCl reservoir.

Figure 3-44. Filling the Electrode Compartment

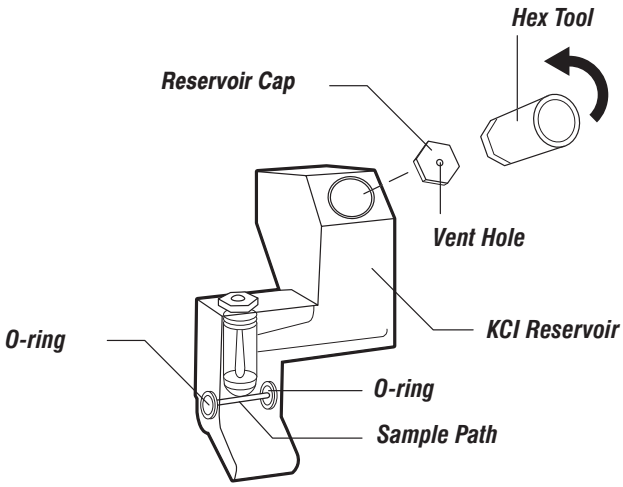


⚠ **CAUTION:** Do not touch the internal electrode wire. The wire is fragile and is easily damaged.

4. Install the internal electrode in the sensor:
   a. Use the hex tool to remove the internal electrode from its container.
   b. Insert the internal electrode into the electrode compartment.
   c. Screw it into place with the hex tool, ensuring that you do not cross-thread the electrode.
   d. Tap the front face of the sensor with your knuckle to release any bubbles.

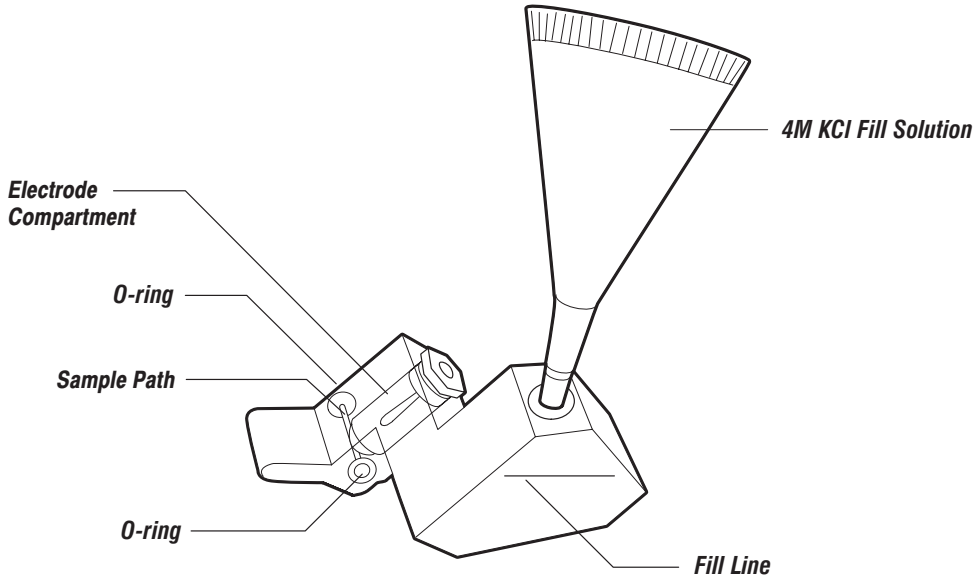
5. Fill the KCl reservoir in the new sensor:
   a. Remove the reservoir cap with the hex tool and set it aside as shown in Figure 3-45.

Figure 3-45. Removing the Reservoir Cap with the Hex Tool



   b. Partially fill the KCl reservoir as shown in Figure 3-46.

Figure 3-46. Filling the Reference Sensor



   c. Tap the front face of the sensor with your knuckle to release any bubbles.
   d. Gradually fill the KCl reservoir with KCl fill solution to the fill line.

CAUTION: Do not overtighten the reservoir cap. Overtightening can deform the gasket and cause leaks.

e. Reinstall the reservoir cap and hand-tighten.

6. Continue with *Reinstalling a Sensor*, page 3-89.

Replacing the Reference Sensor Cassette

Materials required:

- reference electrode refill kit
- hex tool
- lint-free tissue

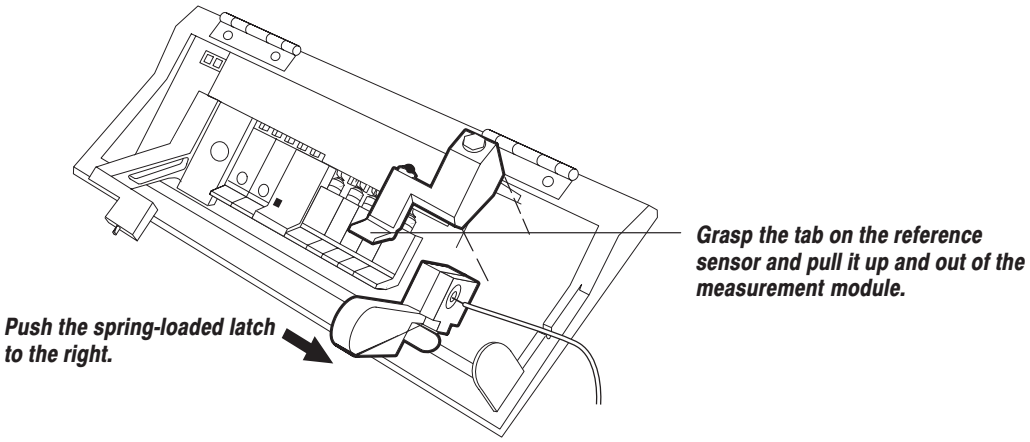
Menu Code 2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

2. Remove the reference sensor as shown in Figure 3-47:
   a. Push up the latches on the measurement module door and lift the door.
   b. Push the spring-loaded latch to the right.
   c. Grasp the tab on the reference sensor and pull the sensor up and out of the measurement module.

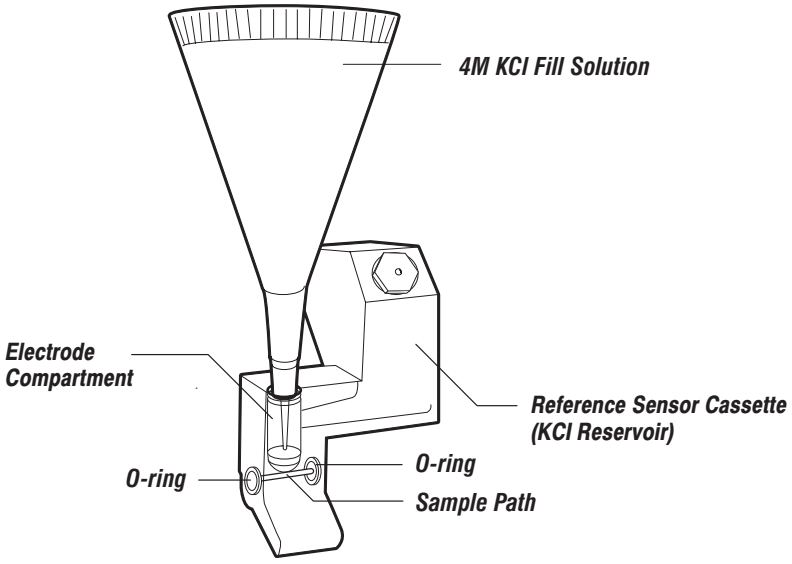
Figure 3-47. Removing the Reference Sensor from an 850



CAUTION: Do not touch the internal electrode wire. The wire is fragile and is easily damaged.

3. Use the hex tool to remove the internal electrode from the cassette you are replacing.
4. Discard the cassette according to your laboratory protocol.
5. Stand the internal electrode on its cap in a safe place.
6. Remove the new reference sensor cassette from its box.
7. Fill the electrode compartment in the new cassette:
   a. Insert the tip of the KCl fill solution container into the electrode compartment as shown in Figure 3-48.
   b. Slowly fill the electrode compartment by gently squeezing the container until the KCl fill solution enters the KCl reservoir.

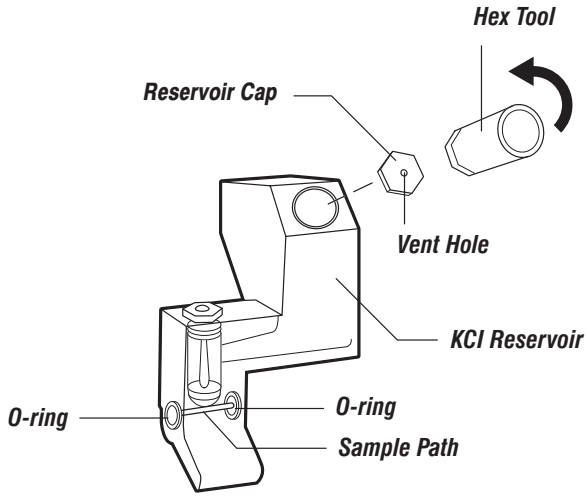
Figure 3-48. Filling the Electrode Compartment



CAUTION: Do not touch the internal electrode wire. The wire is fragile and is easily damaged.

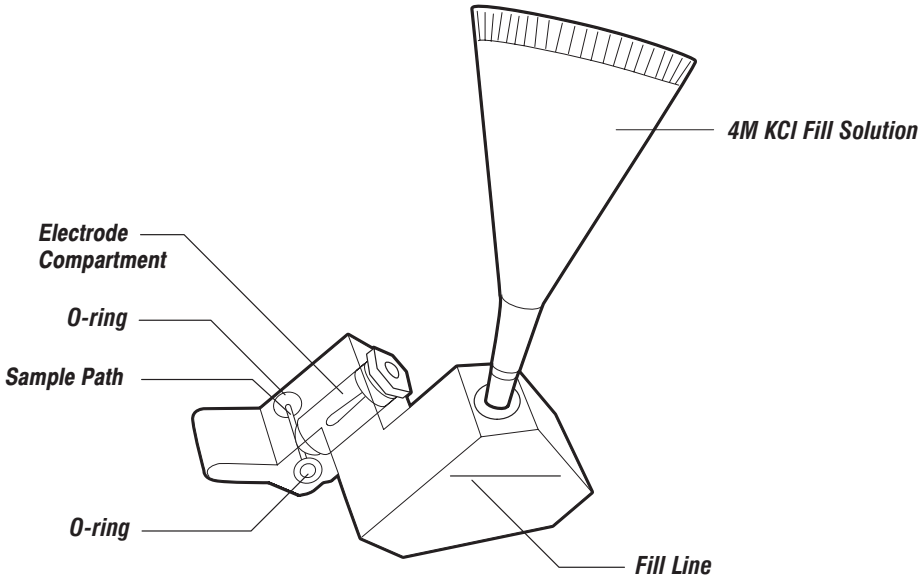
8. Use the hex tool to screw the internal electrode into the electrode compartment, ensuring that you do not cross-thread the electrode.
9. Fill the KCl reservoir in the new sensor:
   a. Remove the reservoir cap with the hex tool as shown in Figure 3-49.

Figure 3-49. Removing the Reservoir Cap with the Hex Tool



b. Partially fill the KCl reservoir as shown in Figure 3-50.

Figure 3-50. Filling the KCl Reservoir



c. Tap the front face of the sensor with your knuckle to release any bubbles.

d. Gradually fill the KCl reservoir with KCl fill solution up to the fill line.

⚠ **CAUTION:** Do not overtighten the reservoir cap. Overtightening can deform the gasket and cause leaks.

e. Reinstall the reservoir cap and hand tighten.

10. Continue with *Reinstalling a Sensor*, page 3-89.

Replacing the Internal Reference Electrode

Materials required:

- reference electrode internal replacement kit
- hex tool
- lint-free tissue

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

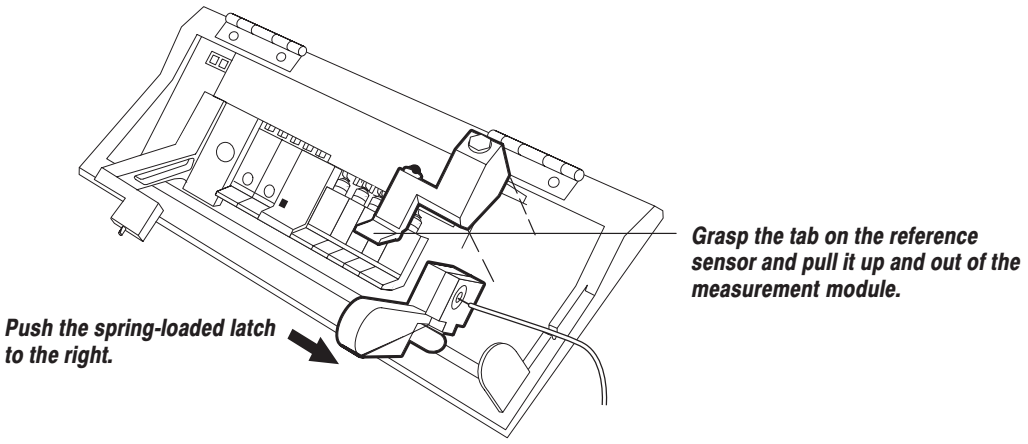
Menu Code
2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

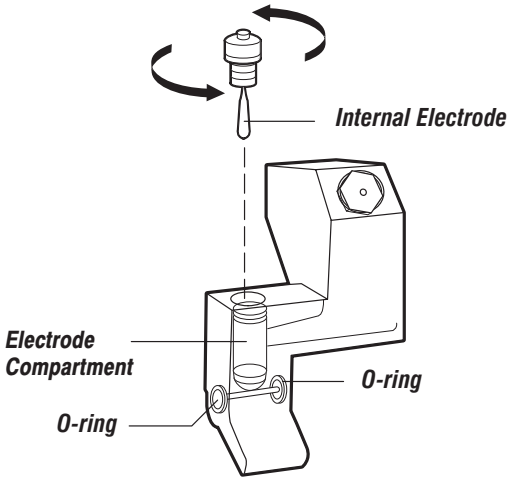
2. Remove the reference sensor as shown in Figure 3-51:
   a. Push up the latches on the measurement module door and lift the door.
   b. Push the spring-loaded latch to the right.
   c. Grasp the tab on the reference sensor and pull the sensor up and out of the measurement module.

Figure 3-51. Removing the Reference Sensor from an 850



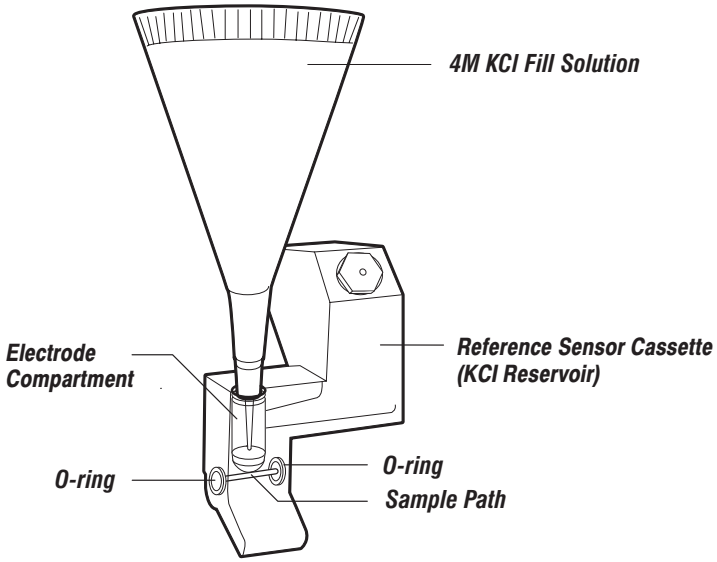
3. Use the hex tool to remove the internal electrode from the reference sensor as shown in Figure 3-52.

Figure 3-52. Removing the Internal Electrode



4. Discard the internal electrode according to your laboratory protocol.
5. Empty the KCl fill solution from the cassette.
6. Add 3 drops of KCl fill solution to the electrode compartment and then drain the compartment.
7. Fill the electrode compartment in the new cassette as shown in Figure 3-53:
   a. Insert the tip of the KCl fill solution container into the electrode compartment in the cassette.
   b. Partially fill the electrode compartment by gently squeezing the KCl fill solution container.
   c. Tap the front face of the sensor with your knuckle to release any bubbles.
   d. Continue filling until the KCl fill solution enters the KCl reservoir.

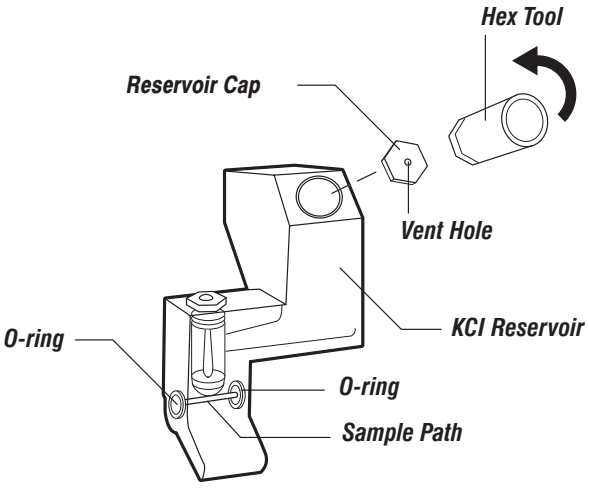
Figure 3-53. Filling the Electrode Compartment



CAUTION: Do not touch the internal electrode wire. The wire is fragile and is easily damaged.

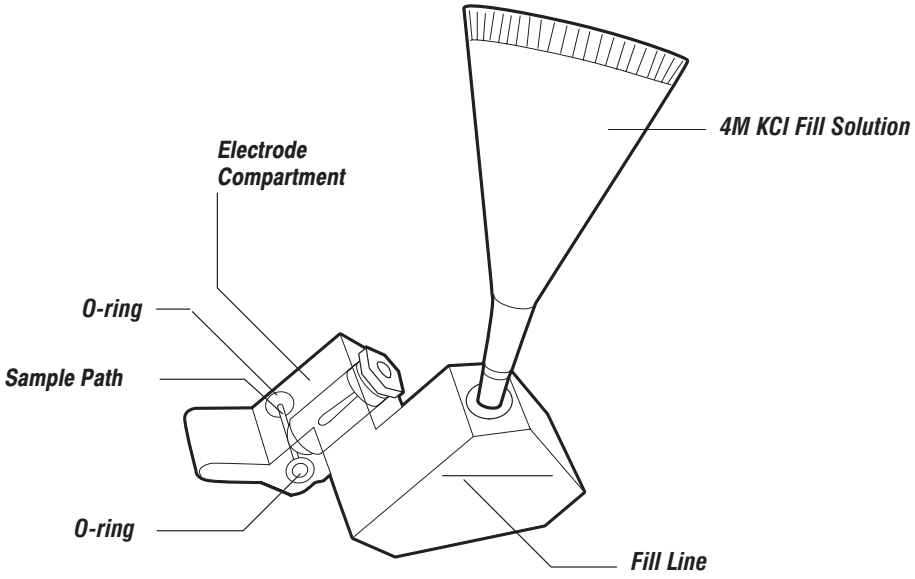
8. Use the hex tool to remove the new internal electrode from its container.
9. Insert the internal electrode into the compartment and screw it into place with the hex tool, ensuring that you do not cross-thread the electrode.
10. Fill the KCl reservoir in the sensor:
    a. Remove the reservoir cap with the hex tool and set it aside as shown in Figure 3-54.

Figure 3-54. Removing the Reservoir Cap with the Hex Tool



    b. Partially fill the KCl reservoir by gently squeezing the KCl fill solution container as shown in Figure 3-55.

Figure 3-55. Filling the KCl Reservoir



c. Tap the front face of the sensor with your knuckle to release any bubbles.

d. Gradually fill the KCl reservoir with KCl fill solution to the fill line.

CAUTION: Do not overtighten the reservoir cap. Overtightening can damage the gasket and cause leaks.

e. Reinstall the reservoir cap and hand-tighten.

11. Continue with *Reinstalling a Sensor*, page 3-89.

Filling the Measurement Sensors

Use this procedure to fill any measurement sensors that do not have sufficient fill solution. Refer to Table 3-1 to determine the appropriate fill solution to use.

Materials required:

- appropriate fill solution
- lint-free tissue

NOTE: If your system has a CO-ox module, follow the procedure described for the appropriate base model. For example, information identified for an 860 also applies to an 865.

NOTE: The pO_2 and pCO_2 sensors do not require fill solution.

860 **NOTE:** The glucose and lactate biosensors do not require fill solution.

Table 3-1. Sensor Fill Solutions

Sensor	*Fill Solution*	*System*
pH	pH	840, 850, 860
Na^+	Na^+, K^+, Cl^-, Ca^{++}	850, 860
K^+	Na^+, K^+, Cl^-, Ca^{++}	850, 860
Cl^-	Na^+, K^+, Cl^-, Ca^{++}	850, 860
Ca^{++}	Na^+, K^+, Cl^-, Ca^{++}	850, 860

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

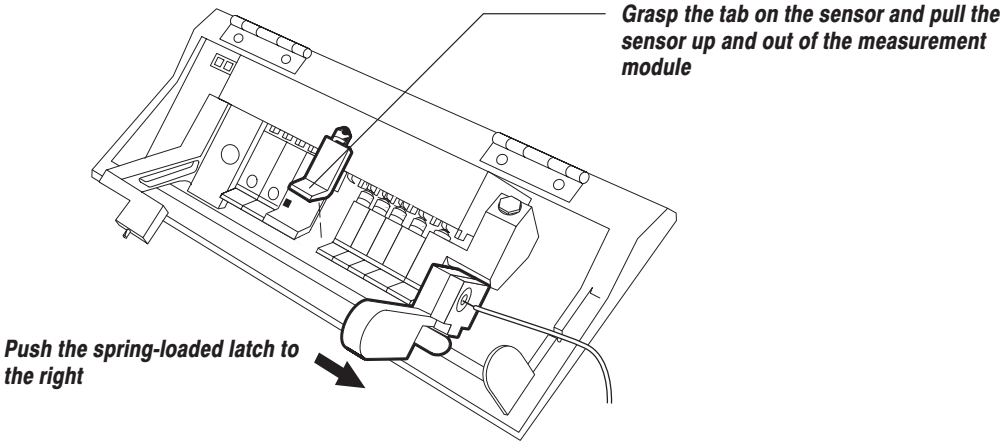
Menu Code
2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

2. Remove the sensor as shown in Figure 3-56:
   a. Push up the latches on the measurement module door and lift the door.
   b. Push the spring-loaded latch to the right.
   c. Grasp the tab on the sensor and pull the sensor up and out of the measurement module.

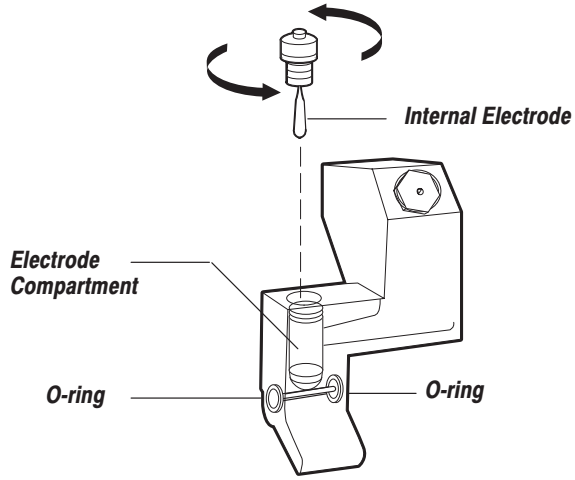
Figure 3-56. Removing a Measurement Sensor from an 850



CAUTION: Do not touch the internal electrode wire. The wire is fragile and is easily damaged.

3. Unscrew the internal electrode and carefully set it aside on a lint-free tissue as shown in Figure 3-57.

Figure 3-57. Removing the Internal Electrode



4. Empty the fill solution remaining in the sensor.

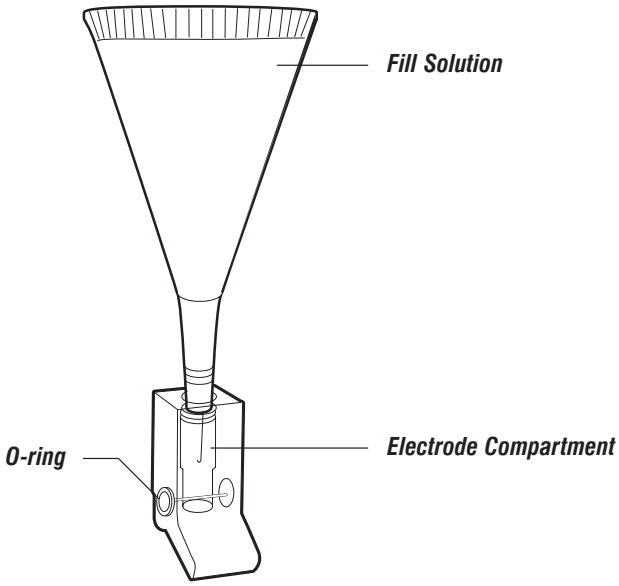
NOTE: Refer to Table 3-1 to determine the appropriate fill solution to use.

5. Rinse the electrode compartment with 3 drops of the appropriate sensor fill solution and then empty the fill solution from the sensor.
6. Slowly add the appropriate fill solution as shown in Figure 3-58:

(850) (860)

- Fill the pH, K^+, Cl^-, and Ca^{++} sensors almost full, leaving a bubble at the top.
- Fill the Na^+ sensor to the top.

Figure 3-58. Filling a Measurement Sensor



7. Insert the internal electrode into the electrode compartment and screw it into place, ensuring that you do not cross-thread the electrode.
8. Continue with *Reinstalling a Sensor*, page 3-89.

Replacing the Measurement or Sample Ground/ Temperature Sensors

If you need to replace the reference sensor, refer to *Replacing the Reference Sensor*, page 3-71.

860 If you need to replace the glucose or lactate biosensors, refer to *Replacing the Glucose and Lactate Biosensors*, page 3-86.

Materials required:

- appropriate sensor

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

NOTE: If your system has a CO-ox module, follow the procedure described for the appropriate base model. For example, information identified for an 860 also applies to an 865.

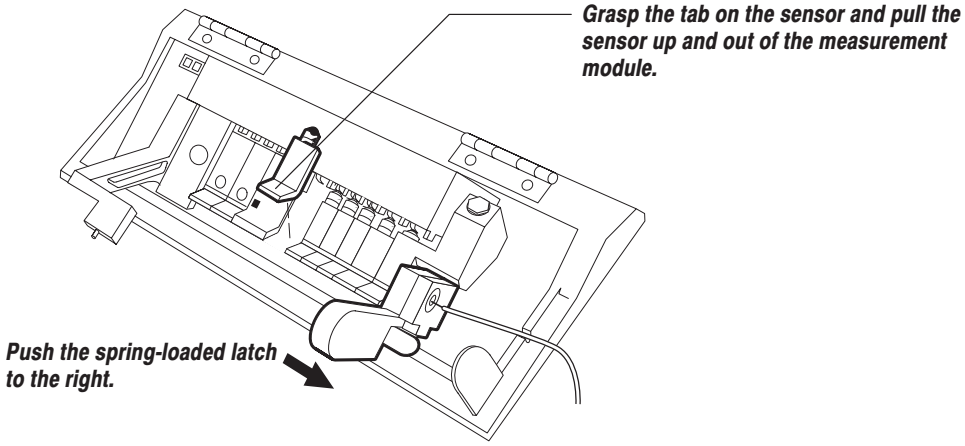
Menu Code
2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

2. Remove the sensor as shown in Figure 3-59:
   a. Push up the latches on the measurement module door and lift the door.

Figure 3-59. Removing a Measurement Sensor from an 850



   b. Push the spring-loaded latch to the right.
   c. Grasp the tab on the sensor and pull the sensor up and out of the measurement module.
   d. Discard the sensor.
3. Perform the appropriate action.

If you are replacing . . .	*Then . . .*
the chloride sensor	go to step 4.
other measurement sensors or the sample ground/temperature sensor	go to step 5.

(850) (860)

4. Fill the chloride sensor with the Na^+, K^+, Cl^-, Ca^{++} fill solution:
   a. Remove the new sensor from the box.

CAUTION: Do not touch the internal electrode wire. The wire is fragile and is easily damaged.

   b. Unscrew the internal electrode and set it aside on a lint-free tissue.
   c. Rinse the electrode compartment with 3 drops of fill solution and then empty it.
   d. Fill the sensor almost full, leaving a bubble at the top.

e. Screw the internal electrode into place, ensuring that you do not cross-thread the electrode.

f. Tap the front face of the sensor with your knuckle to remove bubbles.

g. Wipe any excess fill solution from the exterior of the sensor with a lint-free tissue.

5. Ensure that the O-ring is in place on each sensor.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

NOTE: If the sensor does not easily insert into the measurement module, slide the remaining sensors to the right to create more space.

6. Install the sensor:

   a. Align the top of the sensor with the sensor contact.

   b. Snap the body of the sensor down into place.

   c. Press the tab on the spring-loaded latch down to release the latch.

   d. Verify that the sensors are installed from left to right in the following order in the measurement module:

840	pO_2	pCO_2	GRD	*p*H	Ref					
850	pO_2	pCO_2	GRD	*p*H	K^+	Ca^{++}	Cl^-	Na^+	Ref	
860	pO_2	pCO_2	GRD	Glu	Lac	*p*H	K^+	Ca^{++}	Cl^-	Na^+	Ref

7. Close the measurement module door.

8. Press **Continue** and allow the system to warm up for at least 15 minutes.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

9. Press **No**.

Menu Code
(from the Main Menu)
3 ***2***

10. If you replaced the sample ground/temperature sensor, check the sample path temperature from the Menu screen:

    a. Select **3 Troubleshooting** and press **Enter**.

    b. Select **2 Temp/pAtm** and press **Enter**.

    c. Press **Start Test**.

    d. Press **Stop Test**.

    e. Check the screen for the sample temperature reading.

    f. If you see the message, Temperature control system off, press **Reset Control**.

g. Allow the system to warm up.

h. Press **Exit Test**.

Menu Code
(from the Main Menu)
1 ***2***

11. When the temperature is stable, perform a two-point calibration:

    a. Select **1 Calibration** and press **Enter**.

    b. Select **2 Two-point** and press **Enter**.

    The Ready screen appears when the calibration finishes.

12. Analyze a minimum of two levels of quality control materials to verify sensor performance.

Procedural Notes

After the sensor temperature equilibrates, remove the sensor and inspect for bubbles. As the temperature of the sensor rises to 37°C, gas is driven from the solution, causing bubbles. Remove any bubbles present.

Replacing the Glucose and Lactate Biosensors

Materials required:

- glucose biosensor
- lactate biosensor

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

NOTE: Equilibrate the glucose and lactate biosensors at room temperature (18 to 25°C) for at least 1 hour before use. Keep the biosensors in their foil packages while they are equilibrating.

Menu Code
2 ***7***

1. Stop the system from the Menu screen:

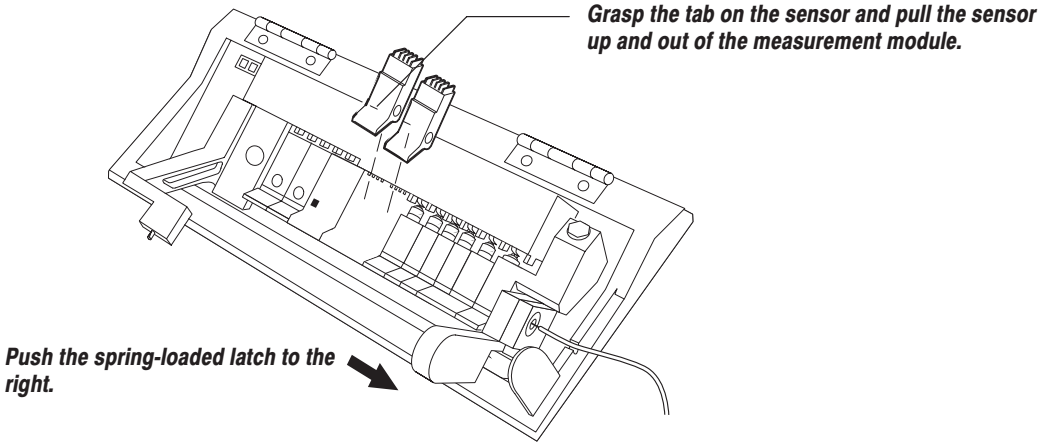
    a. Select **2 Maintenance** and press **Enter**.

    b. Select **7 Stop System** and press **Enter**.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

2. Remove the biosensors as shown in Figure 3-60:

Figure 3-60. Removing the Glucose and Lactate Biosensors



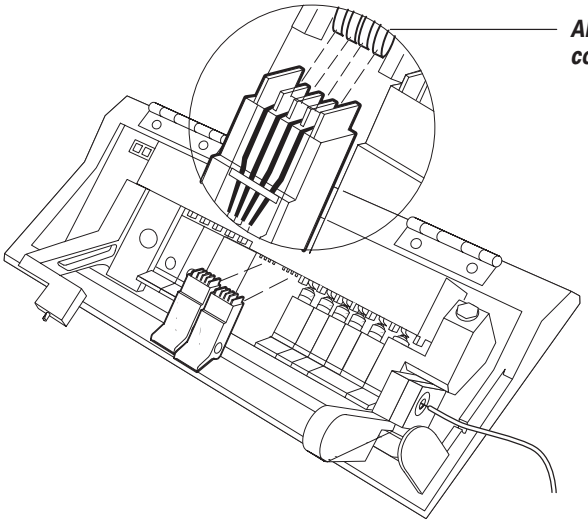
   a. Push up the latches on the measurement module door and lift the door.
   b. Push the spring-loaded latch to the right.
   c. Grasp the tab on the biosensor and pull the biosensor up and out of the measurement module.
   d. Discard the biosensor.
3. Remove the new biosensor from the foil package.
4. Ensure that the O-ring is in place on the biosensor.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

NOTE: As you install the biosensors, ensure that the biosensors are in the correct location. Visually verify that you align the contacts on the biosensors with the contacts in the measurement module. Slide the remaining sensors to the right to create more space, if needed.

5. Install the biosensor:

Figure 3-61. Installing the Glucose and Lactate Biosensors



a. Align the contacts on the biosensor with the contacts in the measurement module.

b. Snap the body of the biosensor down into place. The contacts must be flush with the biosensor.

c. Press the tab on the spring-loaded latch down to release the latch.

d. Verify that the biosensors are installed from left to right in the following order in the measurement module:

pO_2	pCO_2	GRD	Glu	Lac	*p*H	K^+	Ca^{++}	Cl^-	Na^+	Ref

6. Close the measurement module door.

7. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

8. Press **Yes** to perform a two-point calibration.

Menu Code
(from the Main Menu)
1 ***2***

9. Perform two additional two-point calibrations to start hydrating the biosensor as soon as possible:

   a. Move to the Main Menu.

   b. Select **1 Calibration** and press **Enter**.

   c. Select **2 Two-point** and press **Enter**.

10. Allow the biosensors to warm up for at least 30 minutes.

11. Verify that the system temperature is within the acceptable range.

12. Verify biosensor performance by completing two successful two-point calibrations.
13. Analyze a minimum of two levels of quality control material to verify sensor performance.

Reinstalling a Sensor

Use this procedure to reinstall the reference sensor after completing any of the following procedures:

- *Filling the Reference Sensor*, page 3-69.
- *Replacing the Reference Sensor*, page 3-71.
- *Replacing the Reference Sensor Cassette*, page 3-74.
- *Replacing the Internal Reference Electrode*, page 3-77.
- *Filling the Measurement Sensors*, page 3-80.

1. Tap the front face of the sensor with your knuckle to release any bubbles.
2. Wipe any excess fill solution from the exterior of the sensor with a lint-free tissue. On the reference sensor ensure that the vent hole in the reservoir cap is free of KCl crystals.
3. Replace any O-ring that is worn or damaged.
4. Verify that the O-rings are in place.

NOTE: The reference sensor has an O-ring on both sides. The measurement sensors have one O-ring, only on the left side.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

5. Reinstall the sensor:
   a. Align the top of the sensor with the sensor contact.
   b. Snap the sensor into place.
   c. Press the tab on the spring-loaded latch to release the latch.
6. Close the measurement module door.
7. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
8. Allow the system to warm up for at least 15 minutes.
9. Press **Yes** to perform a two-point calibration.

10. Analyze a minimum of two levels of quality control material to verify sensor performance.

Procedural Notes

After the sensor temperature equilibrates, remove the sensor and inspect for bubbles. Remove any bubbles that are present.

Replacing the Gas Tanks

Use this procedure to replace a gas tank or cylinder when the main tank pressure falls below 300 psi.

WARNING Handle compressed gas tanks with caution. To prevent damage and possible personal injury, comply with the following precautions:

- Never drop tanks, allow them to strike each other, or subject them to other strong shocks.
- Secure tanks to a wall or bench, on the floor, or place them in a tank base support stand.
- Avoid dragging, rolling, or sliding tanks, even for short distances. Use a suitable hand truck to move tanks.
- Never tamper with safety devices in regulators or tanks.
- Use these gases for the calibration of clinical and research instrumentation only. Do not dispense these gases for any therapeutic use.
- Do not puncture. Contents are under pressure.
- Do not use or store near heat or open flame.
- Do not expose tanks to temperatures above 54°C (130°F) because contents may vent or explode.
- Never throw tanks into a fire or incinerator. Follow the disposal instructions on the tanks.
- Do not refill tanks. Federal law prohibits the refilling of these tanks.

Materials required:

- Cal Gas or Slope Gas tank
- valve wrench
- soapy water

Menu Code

2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Disconnect the gas line from the system.
3. Remove and dispose of the empty gas tank, as shown in Figure 3-62:

a. Using a valve wrench, close the gas tank by turning the valve stem fully clockwise.

WARNING Do not remove the yoke screw before releasing the gas from the regulator. Gas under pressure can cause bodily injury and property damage.

b. Disconnect the gas regulator from the gas tank by unscrewing the yoke screw. You may hear a short spurt of gas. Remove the regulator.

c. Visually inspect the gas line for cracks and leaks.

d. Remove the gas tank to a well-ventilated, open area.

e. Inspect the gas outlet and ensure that it is free of dirt or other foreign matter.

WARNING Do not come in contact with the gas stream. Gas under pressure can cause bodily injury and property damage.

f. To avoid injury or damage, position the valve outlet so that it is facing away from your face, body, and loose objects.

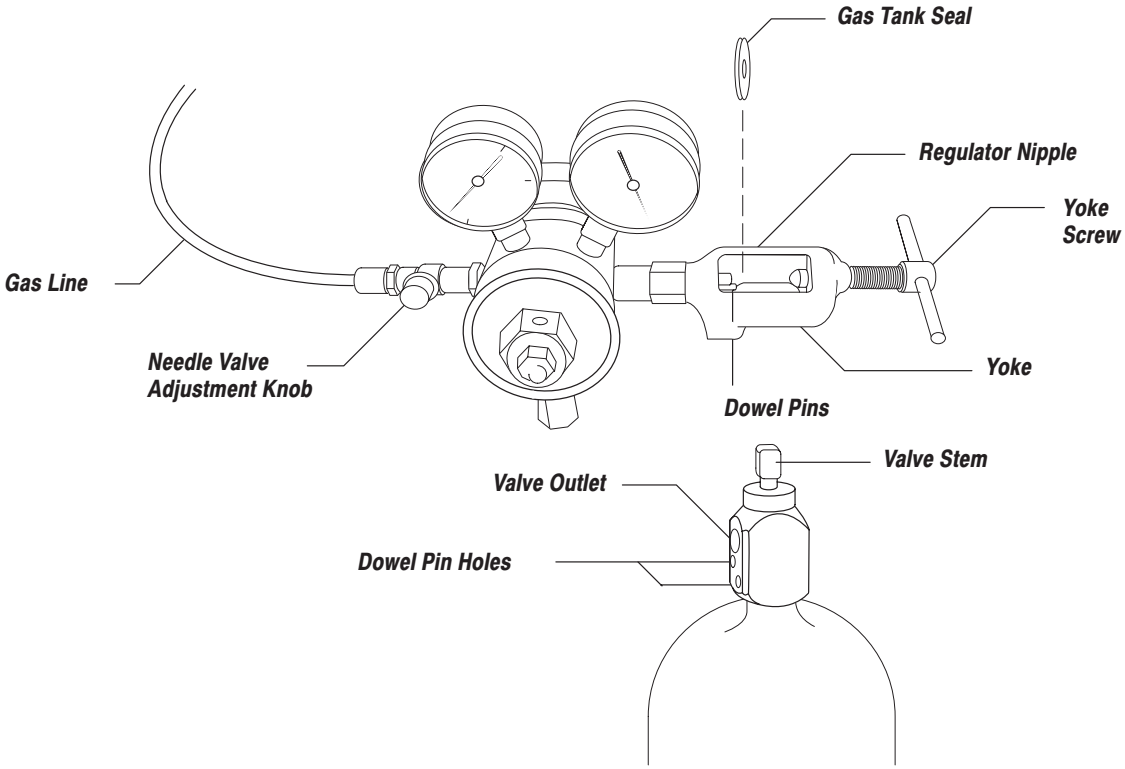
WARNING Do not turn the valve stem more than is necessary to hear gas exiting the valve stem. Gas under pressure can cause bodily injury and property damage.

g. Using a wrench, release the contents of the gas tank by slowly turning the valve stem counterclockwise until you hear gas exiting the valve stem.

h. When the gas tank is completely vented and no more gas is heard exiting the valve, open the valve stem completely to ensure all of the contents is vented.

i. Label the container Empty and dispose of the tank according to your laboratory protocol.

Figure 3-62. Gas Tank Valve Assembly and Regulator



4. Install the new gas tank:
   a. Check the gas tank label to verify that you are installing the correct gas:
      - Bayer Diagnostics Cal Gas contains 5% CO_2 and 12% O_2
      - Bayer Diagnostics Slope Gas contains 10% CO_2 and 0% O_2
   b. Place the gas tank into its final position and secure the tank.
   c. Remove the protective shrink seal from the valve assembly of the gas tank.
   d. Verify that the gas tank seal is in good condition and in place on the regulator, as shown in Figure 3-62.
   e. Attach the gas regulator to the gas tank by aligning the regulator nipple with the valve outlet and ensure that the dowel pins on the regulator-yoke screw line up properly with the holes in the tank valve, as shown in Figure 3-62.
   f. Tighten the yoke screw firmly.

   NOTE: The typical main tank pressure is 2200 psi. The typical regulator valve pressure is 3 to 5 psi.

   g. Slowly open the gas tank by turning the valve stem counterclockwise with the wrench until the pressure gauge on the regulator indicates pressure and then turn it one more turn.

CAUTION: Do not turn the needle valve too hard or damage can occur.

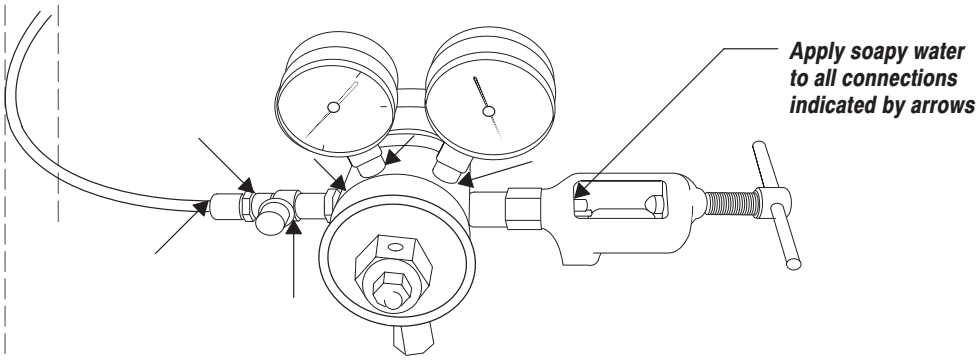
h. Carefully turn the needle valve adjustment knob counterclockwise until until it stops.

i. Listen carefully for any gas leaks.

j. Check the gas line for good gas flow.

k. Visually check for leaks by applying soapy water around all connections, as shown in Figure 3-63, and watching for bubbles.

Figure 3-63. Checking Connections for Leaks



5. If the 800 system will not be used for an extended period of time, close the gas tank by turning the valve stem clockwise.

6. Connect the gas line to the appropriate 800 system port.

7. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

Menu Code
(from the Main Menu)
3 1 4

8. Check the gas flow rate from the Menu screen:

   a. Select **3 Troubleshooting** and press **Enter**.

   b. Select **1 Fluidics System** and press **Enter**.

   c. Select **4 Valves** and press **Enter**.

   d. Select the gas type that you replaced and press **Enter**.

   e. Insert an aspiration adapter into the sample port and immerse the open end of the adapter into a small container of reagent water.

   f. Press **Start Test**.

   g. Verify that a steady stream of bubbles flows into the water.

   h. Press **Stop Test**.

   i. Verify that the bubbles stop flowing into the water.

   j. Remove the adapter.

   k. Press **Exit Test**.

Menu Code
(from the Main Menu)
1 4

9. Perform a gas two-point calibration from the Menu screen:
   a. Select **1 Calibration** and press **Enter**.
   b. Select **4 Gas Two-point** and press **Enter**.

Procedural Notes

Perform two-point calibrations after changing the calibration reagents, including the gas standards, to ensure that the reagents are acceptable and the system is functioning properly. Additionally, you can analyze quality control materials with the new reagents and compare the results with the previous QC results after the system is recalibrated.

If you do not install Bayer Diagnostics Cal Gas or Slope Gas tanks, ensure that you define the calibration gas values for the gases used during calibration, as described in *Defining Calibration Gas Values* in Section 5.

Replacing the Gas Tubing

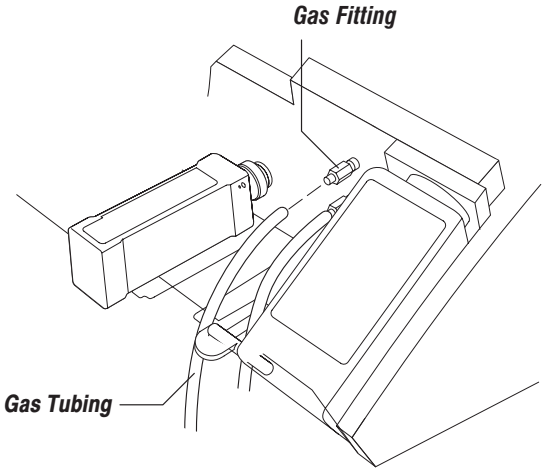
Materials required:

- gas tubing
- valve wrench

Menu Code
2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Using a valve wrench, close the gas tank by turning the valve stem clockwise.
3. Disconnect the tubing from the gas fitting on the reagent manifold as shown in Figure 3-64.

Figure 3-64. Removing the Gas Tubing



4. Disconnect the tubing from the gas regulator and discard the tubing.
5. Connect one end of the new tubing to the fitting on the regulator.
6. Connect the other end of the tubing to the fitting on the reagent manifold.

NOTE: The average main tank pressure is 2200 psi. The average secondary valve pressure is 3 to 5 psi.

7. Slowly open the gas tank by turning the valve stem counterclockwise with the wrench.

   Turn the valve stem approximately 3/4 turn until the regulator pressure gauge indicator stops rising.
8. Open the valve stem one more turn.
9. Listen carefully for any gas leaks.
10. Check for leaks using soapy water and watching for bubbles.
11. Verify that the regulator outlet gauge indicates 3 to 5 psi.
12. Press **Continue**.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
13. Press **No**.

Menu Code
(from the Main Menu)
3 ***1*** ***4***

14. Check the gas flow rate from the Menu screen:
    a. Select **3 Troubleshooting** and press **Enter**.
    b. Select **1 Fluidics System** and press **Enter**.
    c. Select **4 Valves** and press **Enter**.
    d. Select the gas type that you replaced and press **Enter**.
    e. Insert an aspiration adapter into the sample port and immerse the open end of the adapter into a small container of reagent water.
    f. Press **Start Test**.
    g. Verify that a steady stream of bubbles flows into the water.
    h. Press **Stop Test**.
    i. Verify that the bubbles stop flowing into the water.
    j. Remove the adapter.
    k. Press **Exit Test**.

Menu Code
(from the Main Menu)
1 ***4***

15. Perform a two-point calibration from the Menu screen:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **4 Gas Two-point** and press **Enter**.

Replacing a Roller Cage

Use this procedure to replace the roller cage for the reagent, sample, waste, or CO-ox pump.

Materials required:

- reagent water
- lint-free tissue
- roller cage

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

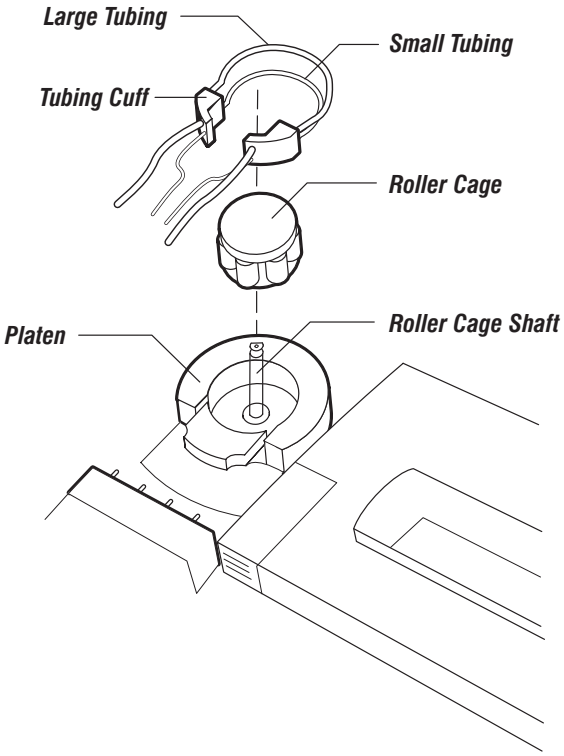
Menu Code
2 ***7***

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Disconnect the pump tubing from the reagent manifold.

NOTE: Do not stretch the tubing.

3. While holding the left side of the tubing, turn the roller cage clockwise and gently pull the tubing away from the platen and the roller cage.
4. Set the tubing assembly aside.
5. Grasp the roller cage and gently pull it straight off its shaft as shown in Figure 3-65.

Figure 3-65. Removing the Reagent Pump Roller Cage



6. Clean the roller cage shaft with a lint-free tissue moistened with reagent water and dry thoroughly.
7. Place the new roller cage on the shaft.
8. Turn the roller cage on the shaft until the roller cage stops.
9. Press the roller cage down until the cage snaps into place.
10. Reinstall the tubing as described in *Replacing the Pump Tubing*, page 3-39.
11. Press **Continue**.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
12. Press **Yes** to perform a two-point calibration.

Replacing the Sample Port

Materials required:

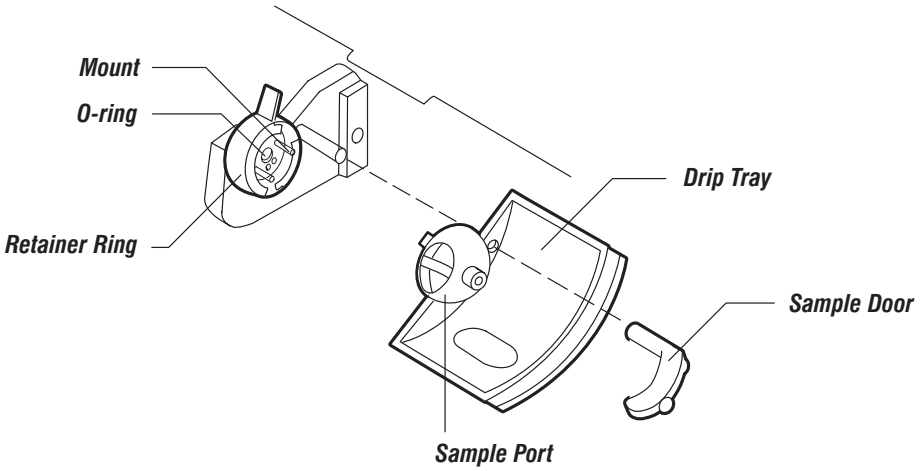
- sample port

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code 2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Pull off the sample door as shown in Figure 3-66.

Figure 3-66. Replacing the Sample Port



3. Grasp the tab on the retainer ring and firmly pull the tab toward you to rotate the ring.
4. Grasp the sample port and attached drip tray and pull it off the mount as shown in Figure 3-66.

NOTE: Ensure that the three O-rings are in place.

5. Install the new sample port on the mount.
6. Push the tab on the retainer ring away from you until it locks into place.
7. Reinstall the sample door, ensuring that it snaps in place.
8. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
9. Press **Yes** to perform a two-point calibration.

Replacing the Sample Probe

Materials required:

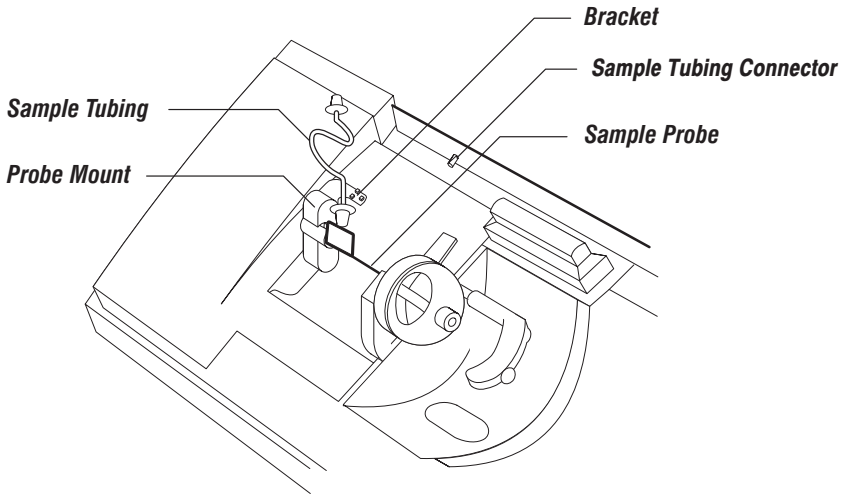
- sample probe

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code
2 7

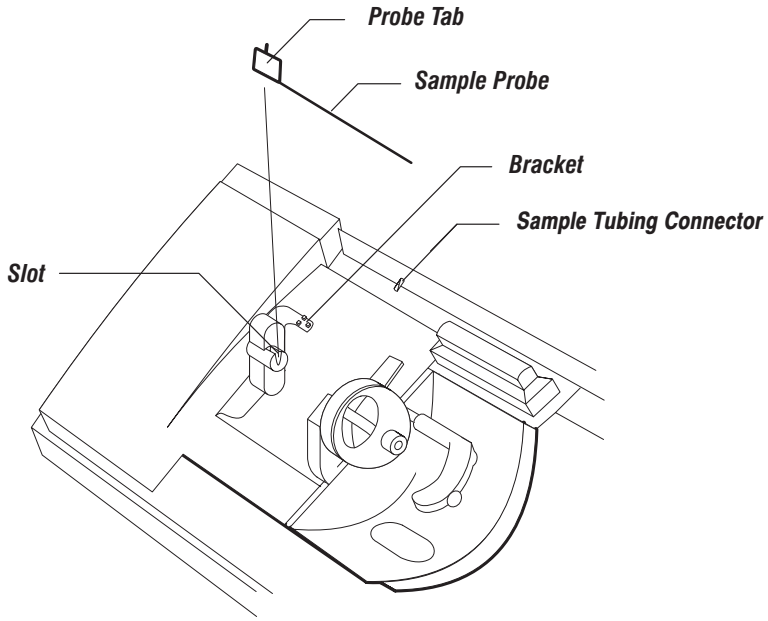
1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Remove the old probe:
   a. Disconnect the sample tubing from the connector on the measurement module.
   b. Disconnect the sample tubing from the bracket on the probe mount.
   c. Rotate the sample tubing toward you by pulling it up until it is perpendicular to the bench top as shown in Figure 3-67.

Figure 3-67. Rotating the Sample Tubing



   d. Disconnect the sample tubing from the sample probe.
   e. Pull the probe tab to the left into the slot, and pull the probe out of the sample port, as shown in Figure 3-68.

Figure 3-68. Replacing the Sample Probe



3. Install the new probe:

CAUTION: Insert the probe slowly to avoid bending the shaft.

a. Push the sample probe into the opening in the sample port and place the probe tab in the slot.

b. Connect the sample tubing to the new sample probe.

c. Rotate the sample probe and tubing down toward the system.

d. Place the sample tubing in the bracket on the probe mount.

e. Connect the sample tubing to the sample tubing connector on the measurement module.

4. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

5. Press **Yes** to perform a two-point calibration.

Replacing the Capillary Seal

Materials required:

- capillary seal

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code 2 7

1. Stop the system from the Menu screen:

a. Select **2 Maintenance** and press **Enter**.

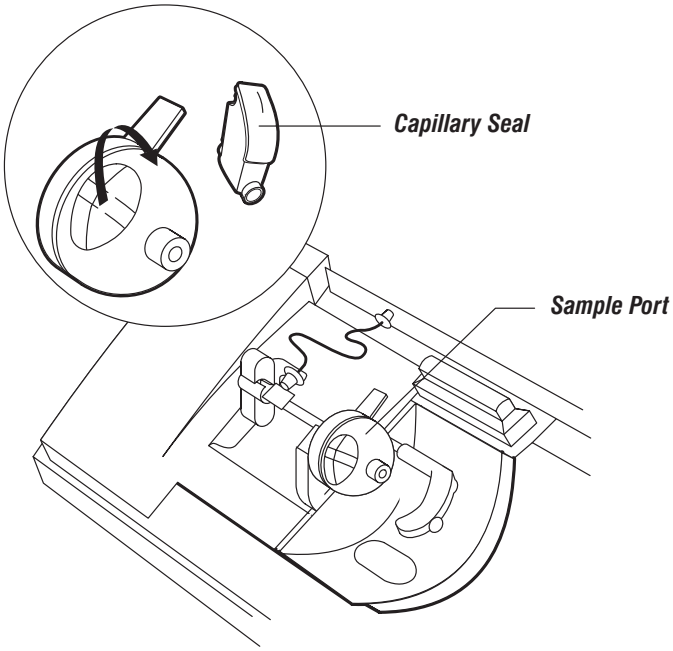
b. Select **7 Stop System** and press **Enter**.

2. Ensure that the sample probe is fully retracted.

3. Remove the old capillary seal:

   a. Grasp the top of the capillary seal and pull it toward the right and out of the sample port, as shown in Figure 3-69.

Figure 3-69. Replacing the Capillary Seal



   b. Discard the capillary seal according to your laboratory protocol.

4. Install the new capillary seal:

   a. Hold the seal at the top, angle it toward the right, and push it into the opening in the sample port.

   b. Insert a capillary tube into the port to ensure that the capillary seal fits securely in place.

5. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

6. Press **Yes** to perform a two-point calibration.

Replacing the Measurement Module Lamp

Materials required:

- measurement module lamp

Menu Code 7 3

1. Shut down the system from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **3 Shutdown** and press **Enter**.
   c. Press **Yes**.

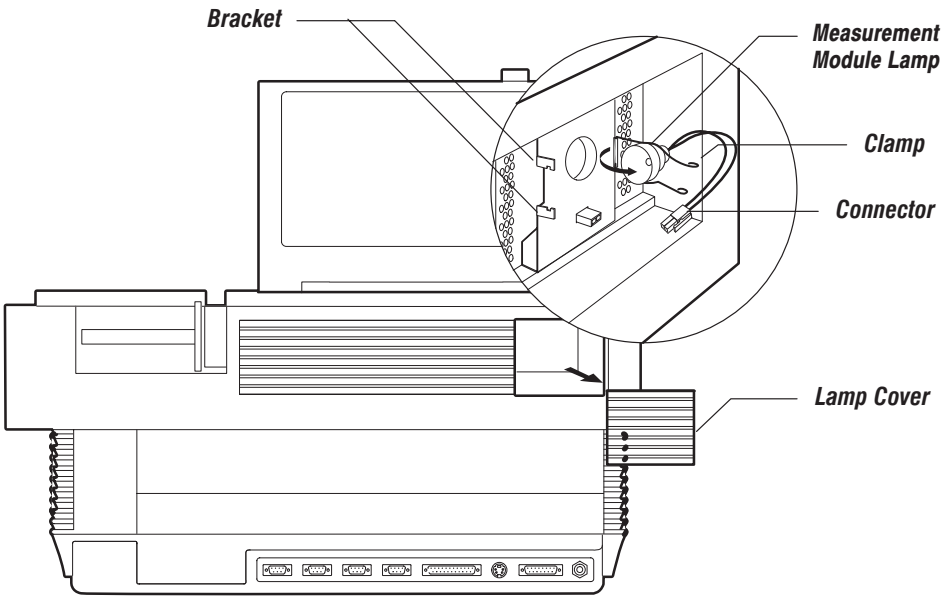
⚠ **CAUTION:** You must wait at least 1 minute before you disconnect the power cord, and then wait at least 10 seconds before you reconnect the power cord. If you do not adhere to the time intervals, you can damage the system.

2. Wait until prompted, and then disconnect the power cord from the power source.
3. Disconnect the power cord from the side panel of the system.
4. Turn the system around so that the rear panel faces you.
5. Push the lamp cover up and remove the cover.

WARNING Ensure that the lamp has been off for at least 5 minutes to allow sufficient time for it to cool.

6. Allow the lamp to cool for at least 5 minutes.
7. Remove the connector from the system as shown in Figure 3-70.

Figure 3-70. Replacing the Measurement Module Lamp



8. Pinch the ends of the clamp and pull it away from the bracket.
9. Remove the old lamp from the clamp and discard it.

CAUTION: Avoid touching the lamp with your fingers.

10. Place a new lamp in the clamp with the front of the lamp facing the system.
11. Pinch the ends of the clamp together and reinstall it in the bracket.
12. Reinstall the connector in the system.
13. Reinstall the lamp cover by inserting the tabs on the cover into the system and snapping the cover back into place.
14. Reconnect the power cord to the power source and allow the system to warm up for at least 15 minutes.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
15. Press **No**.

Menu Code 3 2

16. Verify the system component temperatures from the Menu screen:
    a. Select **3 Troubleshooting** and press **Enter**.
    b. Select **2 Temp/pAtm** and press **Enter**.
    c. Press **Start Test**.
    d. Verify that the system components warm up.
    e. Press **Stop Test**.
    f. If the temperature control system is off, press **Reset Control** and allow the system to warm up.
    g. Press **Exit Test**.

Menu Code ***(from the Main Menu)*** 1 2

17. When the temperature is stable, perform a two-point calibration from the Menu screen:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **2 Two-point** and press **Enter**.

Replacing the CO-ox Lamp

WARNING Burn Hazard. Do not touch or look at the lamp when the lamp is illuminated. Injury to the skin or the eye can occur when the lamp is operated outside the lamp housing.

Materials required:

- CO-ox lamp

Menu Code 2 7

1. Stop the system from the Menu screen:
    a. Select **2 Maintenance** and press **Enter**.

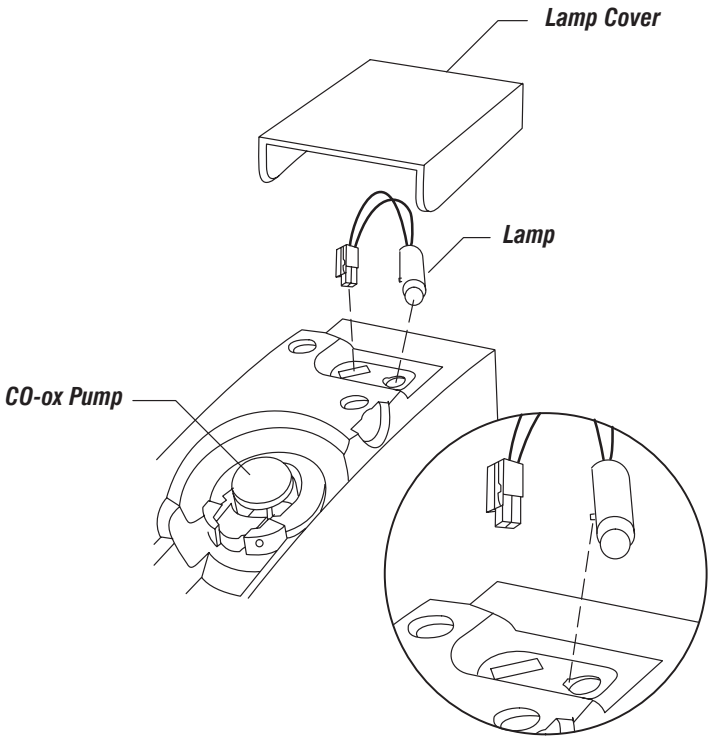
b. Select **7 Stop System** and press **Enter**.

2. Allow the lamp to cool for at least 5 minutes.

WARNING Ensure that the lamp has been off for at least 5 minutes to allow sufficient time for it to cool.

3. Remove the lamp cover from the CO-ox module.
4. Remove the lamp connector, as shown in Figure 3-71.

Figure 3-71. Replacing the CO-ox Lamp



5. Remove the old lamp from the lamp housing and discard it.
6. Place a new lamp in the housing aligning the lamp with the guide pin.
7. Pinch the ends of the clamp together and replace it in the bracket.
8. Install the lamp connector.
9. Reinstall the lamp cover.
10. Press **Continue**.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

11. Press **No**.
12. Calibrate the new lamp:

    a. Select **3 Troubleshooting** and press **Enter**.

Menu Code

3 3 2

b. Select **3 Measurement** and press **Enter**.

c. Select **2 COox Optics** and press **Enter**.

The COox Optics Test screen appears.

13. Press **Start Test**.
14. Check the screen for the message, Lamp test passed.
15. Press **Exit Test**.
16. Press **Exit Menu.**

Menu Code
(from the Main Menu)
1 ***1***

17. Perform a one-point calibration from the Menu screen:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **1 One-point** and press **Enter**.

Replacing the System Fuses

Materials required:

- 2 fuses of the appropriate rating
- small, flat-blade screwdriver

Refer to Table 3-2 to identify the correct fuses for the voltage you use.

Table 3-2. System Fuse Selection

Voltage	*Fuse Rating*	*Fuse Type*
100/120V	4A Slo Blo	5 x 20 mm
220/240V	2A Slo Blo	5 x 20 mm

WARNING To prevent electrical shock or damage to the system, remove power from your system before performing this procedure.

Menu Code
7 ***3***

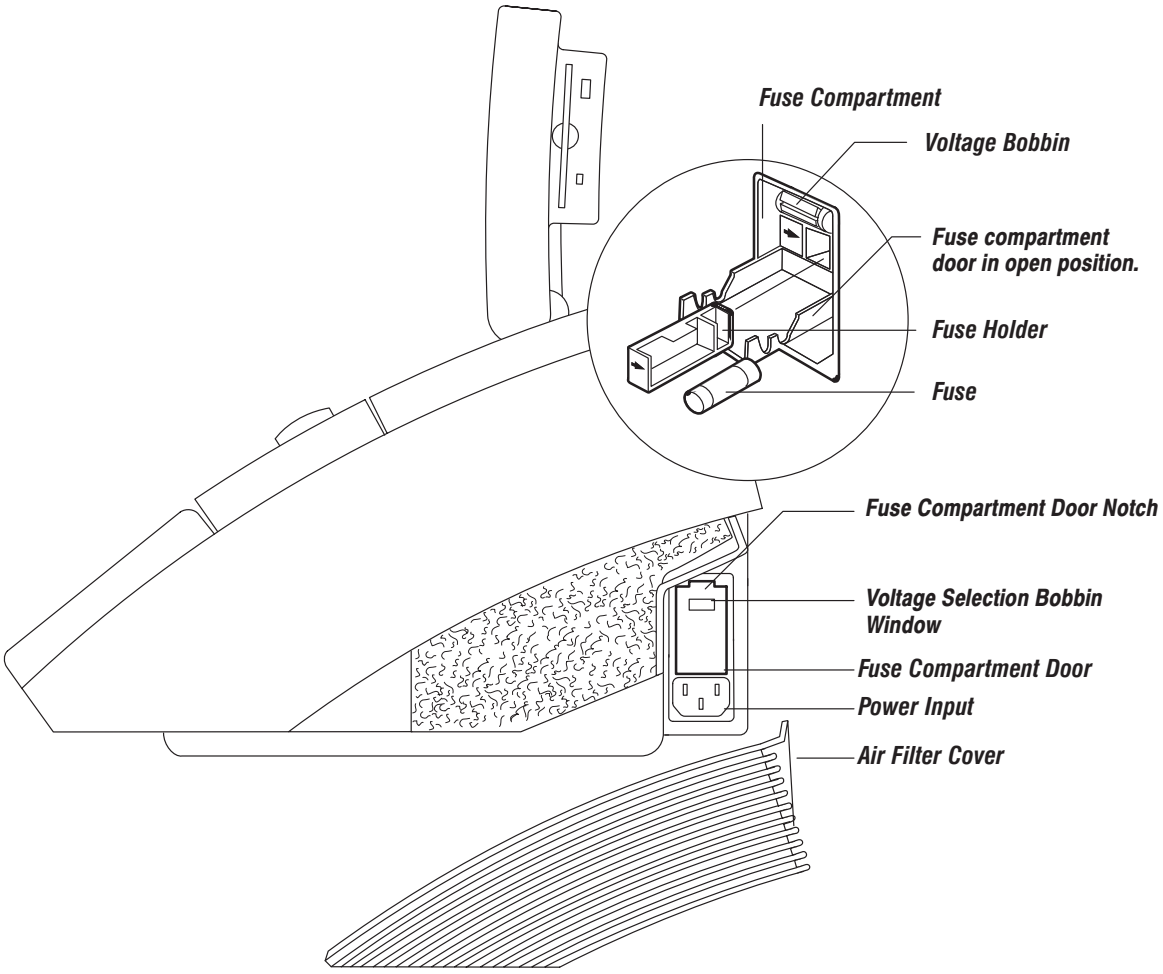
1. Shut down the system from the Menu screen:
    a. Select **7 System Utilities** and press **Enter**.
    b. Select **3 Shutdown** and press **Enter**.
    c. Press **Yes**.

CAUTION: You must wait at least 1 minute before you disconnect the power cord, and then wait at least 10 seconds before you reconnect the power cord. If you do not adhere to the time intervals, you can damage the system.

2. Wait until prompted and then disconnect the power cord from the power source.

3. Disconnect the power cord from the side panel of the system.
4. Remove the air filter cover.
5. With a small, flat-blade screwdriver, gently pry open the fuse compartment door at the top, as shown in Figure 3-72.
6. Remove the fuse holders from the compartment.

Figure 3-72. Replacing the System Fuses



7. Remove the old fuses and install new fuses with the correct rating.

   Refer to Table 3-2 to identify the correct fuse.
8. Slide the fuse holders into the fuse compartment with the arrows pointing to your right.
9. Close the fuse compartment.
10. Ensure that the voltage selection bobbin is in place and the correct setting is visible through the window.
11. Reinstall the air filter cover.

12. Reconnect the power cord to the power source and allow the system to warm up for at least 15 minutes.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

13. Press **No**.

Menu Code
3 ***2***

14. Verify the system component temperatures from the Menu screen:
    a. Select **3 Troubleshooting** and press **Enter**.
    b. Select **2 Temp/pAtm** and press **Enter**.
    c. Press **Start Test**.
    d. Verify that the system components warm up.
    e. Press **Stop Test**.
    f. If the temperature control system is off, press **Reset Control** and allow the system to warm up.
    g. Press **Exit Test**.

Menu Code
(from the Main Menu)
1 ***2***

15. Perform a two-point calibration from the Menu screen:
    a. Select **1 Calibration**, and press **Enter**.
    b. Select **2 Two-point**, and press **Enter**.

4 Troubleshooting the System

Page

Using the Status Event Log

Use this procedure to review and print Status Event Log messages. The Status Event Log stores most diagnostic codes (D codes) and system messages from the last 72 hours of operation. The D codes and system messages listed in the Status Event Log can help you determine what recent events may have contributed to an existing system problem.

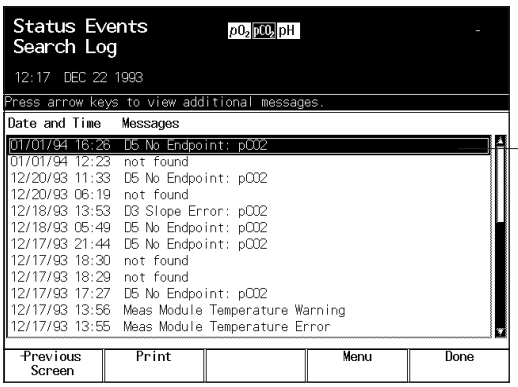
Menu Code
4 ***5***

1. Access the Status Event Log from the Menu screen:
   a. Select **4 Data Recall** and press **Enter**.
   b. Select **5 Status Event Log** and press **Enter**.

   NOTE: The Message Date fields contain the current day's date. Press Done to recall all messages for this day.
2. Type the search criteria and press **Enter** after you complete each field.
3. Press **Done**.
4. Press **Print** to print a list of the entries that met the search criteria.

   Figure 4-1 shows a printed Status Event Log.

Figure 4-1. Status Event Log Report



System Messages

System messages provide information about the operating status of the system and can appear in the status area of the screen, in the Status Event Log, or on printed reports. Table 4-1 describes each system message.

Table 4-1. System Messages

System Message	Description
1-pt Cal Pending in __ Min	Appears 5 minutes before a one-point calibration is due and counts down until the calibration starts.
860 1-pt Metabolite Cal Due	Appears during an analysis to indicate the system will perform a metabolite calibration at the completion of the analysis.
860 1-pt Metabolite Cal Due in __ Min	Appears 5 minutes before a one-point metabolite calibration is due and counts down until the calibration starts.
2-pt Cal Pending in __ Min	Appears 5 minutes before a two-point calibration is due and counts down until the calibration starts.
Additional Messages	Appears in the status area to indicate that there are more messages, which can be viewed in the status log.
Auto Clean Pending in __ Min	Appears 5 minutes before an Auto Clean sequence is due and counts down until the sequence starts.
Bubbles Detected In Sample	Appears when the system detects a non-continuous fluid in the measurement module sample path. See *Troubleshooting System Messages*, page 4-114.
Calibration Overdue: __	Appears when the system must perform a calibration on the sensor(s) indicated.
COox Cover Open During Meas	Appears when the cover of the CO-ox module is open during a sample or slope measurement. Question the results.
COox Cover Open During Zero	Appears when the CO-ox module cover is open during the CO-ox module zero measurement sequence of a one- or two-point calibration. Repeat the calibration with the CO-ox cover closed.
COox Cover is Open	Appears when the cover of the CO-ox module is open when you begin the sample measurement. You must close the cover before pressing Analyze to ensure an accurate CO-ox analysis.

(Continued)

System Message	Description
COox Sample Chamber Temp Error	Appears when the CO-ox sample chamber temperature is not in range. The system cannot accept tHb sample measurement requests. See *Troubleshooting System Messages*, page 4-114.
COox Sample Temp Out of Range	Appears when the CO-ox sample chamber temperature is not in range at the end of measurement sequence. See *Troubleshooting System Messages*, page 4-114.
Correlation Adjustment	Appears when the correlation coefficient is changed.
Data Entry Incomplete	Appears when required data entry fields were not completed.
Device Connected to Port __	Appears after you configure an 800 system for an external device and the connection is established.
Excessive Bubbles in COox Sample	Appears when the system detects a non-continuous fluid (sample or QC material) in the sample chamber and cannot complete the analysis. See *Troubleshooting System Messages*, page 4-115.
Excessive Bubbles in COox Zero	Appears when the system detects a non-continuous fluid (7.3 buffer) in the sample chamber and cannot perform the zero. See *Troubleshooting System Messages*, page 4-115. **NOTE:** The CO-ox module is zeroed during the loading of the 7.3 buffer during a one- or two-point calibration.
Excessive Bubbles in tHb Slope	Appears when the system detects a non-continuous fluid (slope material) in the sample chamber and cannot slope the CO-ox module. See *Troubleshooting System Messages*, page 4-115.
Excessive Scatter in COox Meas	Appears when the lipid level detected in the CO-ox sample exceeds the expected physiological maximum. Also appears if the hemolyzer is disconnected. See *Troubleshooting System Messages*, page 4-115.
File (file number) Outdated QC	Notifies you that a specific QC file is outdated.
If Blood, Question Data	Optical measurements indicate that the CO-oximeter results should be reviewed. A question mark (?) is printed next to the CO-oximeter results on reports. See *Troubleshooting System Messages*, page 4-116.

(Continued)

	System Message	Description
860	Interfering Substance: Glu	Appears when the system detects substances in the sample that may interfere with glucose measurement. See *Troubleshooting System Messages*, page 4-118. **NOTE:** Repeated, unexpected occurrence of this message may indicate sensor failure. See *Troubleshooting Patient Results*, page 4-98.
860	Interfering Substance: Lac	Appears when the system detects substances in the sample that may interfere with lactate measurement. See *Troubleshooting System Messages*, page 4-118. **NOTE:** Repeated, unexpected occurrence of this message may indicate sensor failure. See *Troubleshooting Patient Results*, page 4-98.
	Interfering Substance: tHb	Appears when the CO-ox module detects the presence of substances in the sample that may interfere with CO-ox measurement and will try to correct the measurement to account for the substance. See *Troubleshooting System Messages*, page 4-118.
	Insufficient COox Sample	Appears when there is not enough sample to fill the CO-ox sample chamber, so the measurement cannot be completed. See *Troubleshooting System Messages*, page 4-117.
	Insufficient Sample	Appears when there is not enough sample to fill the measurement block and you manually position the sample for measurement. See *Troubleshooting System Messages*, page 4-118.
	Maintenance Due Today	Appears when a scheduled, non-daily maintenance task is due to be performed.
	Meas Module Door Open	Appears when the measurement module door is open.
	Meas Module Temperature Error	Appears when the measurement module temperature is out of range and the system cannot accept sample analysis requests. See *Troubleshooting System Messages*, page 4-119.
	Meas Module Temperature Warning	Appears when the temperature of the measurement module is outside of the 37 ± 0.15°C range but can accept sample analysis requests. See *Troubleshooting System Messages*, page 4-119.
	No Paper In Printer	Appears when the system detects that there is no paper in the roll printer.

(Continued)

System Message	Description
No Sample Device Detected	Appears when you press Analyze, the sample door closes, and no device is detected in the sample port. See *Troubleshooting System Messages,* page 4-120.
No Waste Bottle Detected	Appears when the waste bottle is not installed.
__ Not Sent	Appears when you press Do Not Send at the end of analysis.
Out of Range	Appears when results for a parameter are out of the measurement range.
Probe Detected Obstruction	Appears when the probe hits an obstruction such as the plunger because there is insufficient sample.
Report Results with Cal Drift	Appears when results are reported for a sensor that exhibits calibration drift.
Sample Temperature Out of Range	Appears when the measurement block temperature is not in range at the end of measurement sequence. See *Troubleshooting System Messages,* page 4-120.
__ Sent	Appears when you press Send at the end of analysis or if results are sent automatically.
SulfHb > 1.5%	Appears when the CO-ox module detects a concentration of SulfHb greater than 1.5%.
tHb Slope Calibration Due	Appears when you need to perform a tHb Slope calibration for the CO-ox module.
Unexpected Device Detected	Appears if the system detects an unexpected device, such as when a sample device is inserted as the door attempts to close to perform an automatic sequence.
Waste Full	Appears when the waste bottle can no longer accept waste.
Waste Is Almost Full	Appears when the waste bottle is near capacity and can accept waste from three more samples.

Troubleshooting D Codes

This section describes the 800 system diagnostic codes (D codes) and messages, the conditions that cause them, and possible solutions. D codes identify changes in the system operation that require corrective action. Some D codes also contain a qualifier after the message.

The qualifier indicates a specific condition related to the D code. For example, D2 indicates excessive drift for a sensor. The qualifier identifies the sensor that has excessive drift. The D code, D2 Excessive Drift pO_2, indicates that the pO_2 sensor has excessive drift. A qualifier that is a number, such as the number 6 in D35 Electronics Error (6), is important information for the Service Representative.

The system displays D codes in the status area. When the system displays a D code, the View Status F-key appears on the screen. The Not Ready screen appears if the D code prevents the system from being ready. Press **View Status** to display the View Status screen.

The View Status screen lists D codes and messages on the left side. The right side of the screen displays possible solutions associated with the D code that is highlighted on the left side.

Press **Troubleshooting** to access the list of system diagnostic tests. Use these tests to troubleshoot D code problems as required.

The section that follows identifies each D code and message, describes the problems that cause the D code, and provides a list of solutions arranged in the appropriate sequence for the problem.

Perform the procedures in sequence until you resolve the problem. If you cannot resolve the problem, contact your Bayer Diagnostics Service Representative.

D2 pO_2 pCO_2 D2 Excessive Drift:

Problem

Sensor drift is beyond predefined limits during a one-point or a two-point calibration.

Qualifiers: pO_2 pCO_2

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct this D code.

If a D2 for pCO_2, with a drift greater than 4.0 mmHg, occurs twice in a 4-hour period and no drift occurs for pO_2, perform QC analysis. If the pCO_2 result is out of range, replace the sensor.

Ensure that the gas tank pressures are greater than 300 psi. Ensure that the Cal Gas and Slope Gas tanks are connected to the correct gas fittings. Ensure that all connections are tight. If the pressure is too low, replace the affected gas tanks as described in *Replacing the Gas Tanks* in Section 3.

Deproteinize the sample path as described in *Deproteinizing the Sample Path* in Section 3.

Check for cracks or leaks in the sample tubing. If necessary, replace the sample tubing as described in *Replacing the Sample Tubing* in Section 3.

Check for leaks or crimps in the gas tubing. If necessary, replace the gas tubing as described in *Replacing the Gas Tubing* in Section 3.

Check the gas flow rate and valve operation for Cal Gas and Slope Gas as described on page 4-64. Perform the Valves Test as described on page 4-62.

Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed. Remove and install the sensors correctly if necessary, as described in *Removing and Checking the Sensors* on page 4-65.

Perform the Measurement test for the affected sensor as described in *Measurement Test*, page 4-70.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/ Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

pH	K^+	Ca^{++}	Cl^-	Na^+

D2 Excessive Drift: D2

Problem

Sensor drift is beyond predefined limits during a one-point or a two-point calibration.

Qualifiers: pH K^+ Ca^{++} Cl^- Na^+

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct this D code.

If more than one sensor has excessive drift, check the reference sensor for KCl leaks as described in *Cleaning the Reference Sensor and Removing Bubbles* in Section 3.

Check the expiration dates and the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents, prime the system, and perform a two-point calibration.

Deproteinize and condition as described in *Deproteinizing the Sample Path* and *Conditioning the Sensors* in Section 3.

Check the solution level in the affected measurement sensor and look for bubbles. If the solution level is low, refill the sensor as described in *Filling the Measurement Sensors* in Section 3.

Check the solution level in the reference sensor and look for salt in the vent hole, bubbles in the sensor, or leaks. If the solution level is low or salt, bubbles, or leaks are present, clean and refill the reference sensor as described in *Cleaning the Reference Sensor and Removing Bubbles* and *Filling the Reference Sensor* in Section 3.

Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Check the sensor contacts and measurement block for salt buildup. Check behind the sensors for fluid leaks that can come from the reference sensor. If salt or leaks are present, clean the sensor with reagent water, dry, and perform a two-point calibration after reinstalling the sensor.

Perform the Measurement Test as described on page 4-70.

Check the diverter valve to verify that the valve is working by performing the Valves test as described on page 4-62.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/ Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

Glu | Lac

D2 Excessive Drift: D2

Problem

Sensor drift is beyond predefined limits during a one-point or a two-point calibration.

Qualifiers: Glu Lac

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, D29, or D50, correct these problems first, then correct this D code.

Check the expiration dates and the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents, and perform a two-point calibration.

Check that the biosensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Check the biosensor contacts and measurement block for salt buildup. Check behind the biosensor for fluid leaks that can come from the reference sensor. If salt or leaks are present, clean the sensors with reagent water, dry, and perform a two-point calibration after reinstalling the biosensors.

Perform the Measurement Test for the affected biosensor as described in *Measurement Test*, page 4-70.

Check the diverter valve to verify that the valve is working. Perform the *Valve Test* as described on page 4-62.

If the glucose or lactate biosensors have been on the system less than 1 day, the sensors may require additional time to hydrate the membranes.

Replace the glucose or lactate biosensor as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.

D2 tHb

D2 Excessive Drift:

Problem

The tHb slope is beyond predefined limits during the calibration.

Qualifiers: tHb

Solutions

Ensure the target value entered for the tHb slope is correct for the slope reagent used. If required, re-enter the value and repeat the tHb slope calibration.

Deproteinize the sample path as described in *Deproteinizing the Sample Path* in Section 3. Repeat the tHb slope calibration.

Check that the sample chamber is tightly in place. Refer to *Cleaning the Sample Chamber*, in Section 3. The tab on the cams should be vertical. Repeat the tHb slope calibration.

Check that the gasket in the sample chamber is seated correctly.

If the D code reappears, contact your Service Representative.

pO_2 | pCO_2

D3 Slope Error: D3

Problem

Sensor slope is beyond predefined limits during a two-point calibration.

Qualifiers: pO_2 pCO_2

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct this D code.

Perform a gas two-point calibration.

Ensure that the gas tank pressures are greater than 300 psi. Ensure that the Cal Gas and Slope Gas tanks are connected to the correct gas fittings. Ensure that all connections are tight. If necessary, replace the affected gas tanks, as described in *Replacing the Gas Tanks* in Section 3.

Check for cracks or leaks in the sample tubing. If necessary, replace the sample tubing, as described in *Replacing the Sample Tubing* in Section 3.

Check for leaks or crimps in the gas tubing. If necessary, replace the gas tubing, as described in *Replacing the Gas Tubing* in Section 3.

Check the gas flow rate and valve operation for Cal Gas and Slope Gas as described on page 4-64. Perform the Valves Test as described on page 4-62.

Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed. Remove and install the sensors correctly if necessary, as described in *Removing and Checking the Sensors* on page 4-65.

Perform the Measurement Test for the affected sensor as described in *Measurement Test*, page 4-70.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/ Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

D3 | pH | K^+ | Ca^{++} | Cl^- | Na^+ D3 Slope Error:

Problem

Sensor slope is beyond predefined limits during a two-point calibration.

Qualifiers: pH K^+ Ca^{++} Cl^- Na^+

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct this D code.

Perform a two-point calibration.

Check the expiration dates and the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents, prime the system, and perform a two-calibration.

Deproteinize the sample path and condition the sensors as described in *Deproteinizing the Sample Path* and *Conditioning the Sensors* in Section 3.

Check the solution level in the affected measurement sensor and look for bubbles. The pH, K^+, Ca^{++}, and Cl^- sensors should be nearly full. The Na^+ sensor should be full. If the solution level is low, refill the sensor as described in *Filling the Measurement Sensors* in Section 3.

Check the sensor contacts and measurement block for salt buildup. Check behind the sensor for fluid leaks that can come from the reference sensor. If salt or leaks are present, clean the sensor with reagent water, dry, and perform a two-point calibration after reinstalling the sensor.

Perform the Measurement Test for the affected sensor as described on page 4-70.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/ Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

Glu | Lac

D3 Slope Error: D3

Problem

Sensor slope is beyond predefined limits during a one- or two-point calibration.

Qualifiers: Glu Lac

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, D29, or D50, correct these problems first, then correct this D code.

Perform a two-point calibration.

Check the expiration dates and the levels of the reagents. Ensure that the bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents, and perform a two-point calibration.

Check that the biosensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Check the biosensor contacts and measurement block for salt buildup. Check behind the biosensor for fluid leaks that can come from the reference sensor. If salt or leaks are present, clean the sensors with reagent water, dry, and perform a two-point calibration after reinstalling the biosensors.

Perform the Measurement Test for the affected biosensor as described on page 4-70.

If the glucose or lactate biosensors have been on the system less than one day, then perform three two-point calibrations.

Replace the glucose or lactate biosensors as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.

If the D code reappears, contact your Service Representative.

D3 tHb

D3 Slope Error:

Problem

The tHb slope is beyond predefined limits during the calibration.

Qualifiers: tHb

Solutions

Ensure the target value entered for the tHb slope is correct for the reagent used. If required, re-enter the value and repeat the calibration.

Ensure the slope reagent is appropriate for the instrument.

Check that the sample chamber is tightly in place. The tab on the cams should be vertical. Repeat the tHb slope calibration.

Check that the gasket in the sample chamber is seated correctly. Refer to *Cleaning the Sample Chamber,* in Section 3. Replace the gasket, if necessary.

If the D code reappears, contact your Service Representative.

pO_2 | pCO_2

D4 Offset Error: D4

Problem

Sensor offset is beyond predefined limits during a one-point or a two-point calibration.

Qualifiers: pO_2 pCO_2

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct the D4.

Perform a gas two-point calibration.

Check for cracks or leaks in the sample tubing. If necessary, replace the sample tubing as described in *Replacing the Sample Tubing* in Section 3.

Ensure that the gas tank pressures are greater than 300 psi. Ensure that the Cal Gas and Slope Gas tanks are connected to the correct gas fittings. Ensure that all connections are tight. If necessary, replace the affected gas tanks as described in *Replacing the Gas Tanks* in Section 3.

Check for leaks or crimps in the gas tubing. If necessary, replace the gas tubing as described in *Replacing the Gas Tubing* in Section 3.

Check the gas flow rate and valve operation for Cal Gas and Slope Gas as described on page 4-64. Perform the Valves Test as described on page 4-62.

Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Perform the Measurement Test for the affected sensor as described in *Measurement Test*, page 4-70.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/ Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

D4 | pH | K^+ | Ca^{++} | Cl^- | Na^+ D4 Offset Error:

Problem

Sensor offset is beyond predefined limits during a one-point or a two-point calibration.

Qualifiers: pH K^+ Ca^{++} Cl^- Na^+

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct the D4.

Perform a two-point calibration.

Check the expiration dates and the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents, and perform a two-point calibration.

Check the solution level in the affected measurement sensor and look for bubbles. The pH, K^+, Ca^{++}, and Cl^- sensors should be nearly full. The Na^+ sensor should be full. If the solution level is low, refill the sensor as described in *Filling the Measurement Sensors* in Section 3.

850 860 **NOTE:** If K^+ or Ca^{++} have a D4 Offset Error, replace the fill solution even if the fluid levels are sufficient.

If more than two sensors have the D4 Offset Error, check the solution level in the reference sensor and look for salt in the vent hole, bubbles in the sensor, or leaks. If the solution level is low or salt, bubbles, or leaks are present, clean and refill the reference sensor as described in *Cleaning the Reference Sensor and Removing Bubbles* and *Filling the Reference Sensor* in Section 3.

Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Perform the Measurement Test for the affected sensor as described in *Measurement Test*, page 4-70.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/ Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

Glu | Lac

D4 Offset Error: D4

Problem

Sensor offset is beyond predefined limits during a two-point calibration.

Qualifiers: Glu Lac

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, D29, or D50, correct these problems first, then correct the D4.

Check that the biosensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Check the expiration dates and the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents, and perform a two-point calibration.

If the glucose or lactate biosensors have been on the system less than one day, then perform three two-point calibrations.

Replace the biosensor as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.

If the D code reappears, contact your Service Representative.

D5 pO_2 pCO_2 D5 No Endpoint:

Problem

Sensor does not reach stable reading within predefined time limit.

Qualifiers: pO_2 pCO_2

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct the D5.

If a D5 for pCO_2 occurs twice in a 4-hour period, perform QC analysis. If the pCO_2 result is out of range, replace the sensor.

Ensure measurement module door was not opened during measurement. If door was opened, repeat the sample analysis.

Perform a gas two-point calibration.

Deproteinize the sample path as described in *Deproteinizing the Sample Path* in Section 3.

Perform the Measurement Test for the affected sensor as described in *Measurement Test*, page 4-70.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/ Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

pH	K^+	Ca^{++}	Cl^-	Na^+

D5 No Endpoint: D5

Problem

Sensor does not reach stable reading during predefined time limit.

Qualifiers: pH K^+ Ca^{++} Cl^- Na^+

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, or D29, correct these problems first, then correct the D5.

Perform a two-point calibration.

Deproteinize the sample path and condition the sensors as described in *Deproteinizing the Sample Path* and *Conditioning the Sensors* in Section 3.

Check the solution level in the affected measurement sensor and look for bubbles. The pH, K^+, Ca^{++}, and Cl^- sensors should be nearly full. The Na^+ sensor should be full. If the solution level is low, refill the sensor as described in *Filling the Measurement Sensors* in Section 3.

Check the solution level in the reference sensor and look for salt in the vent hole, bubbles in the sensor, or leaks. If the solution level is low or salt, bubbles, or leaks are present, clean and refill the reference sensor as described in *Cleaning the Reference Sensor and Removing Bubbles* and *Filling the Reference Sensor* in Section 3.

Check the sensor contacts and measurement block for salt buildup. Check behind the sensors for fluid leaks, which can come from the reference sensor. If salt or leaks are present, clean the sensor with reagent water, dry, and perform a two-point calibration after reinstalling the sensor.

Perform the Measurement Test for the affected sensor as described in *Measurement Test*, page 4-70.

Replace the affected sensor as described in *Replacing the Measurement or Sample Ground/Temperature Sensors* in Section 3.

If the D code reappears, contact your Service Representative.

D5 | Glu | Lac

D5 No Endpoint:

Problem

Sensor does not reach stable reading during predefined time limit.

Qualifiers: Glu Lac

Solutions

NOTE: If D codes also exist for reagent problems such as D23, D24, D29, or D50, correct these problems first, then correct the D5.

Perform a metabolite two-point calibration.

Perform the Measurement Test for the affected biosensor as described in *Measurement Test*, page 4-70.

If the glucose or lactate biosensors have been on the system less than one day, then perform three two-point calibrations.

Replace the biosensor as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.

If the D code reappears, contact your Service Representative.

D12 Sample Door Position Error D12

Problem

Sample door detector cannot determine whether the sample door is open or closed.

Solutions

Check that your hand does not prevent the door from closing.

Check that the door is installed correctly.

Perform the Sample Entry Test as described on page 4-67.

If the D code reappears, contact your Service Representative.

D13 D13 No Sample Detected at FD1

Problem

Fluid detector 1 (FD1) does not detect the sample during the predefined time limit.

Solutions

Check the sample entry components for obstructions and the sample path for blood clots. If obstructions are found press Stop as prompted in the message box. Remove them as described in *Removing Obstructions from the Sample Entry Components* page 4-79.

NOTE: Perform a two-point calibration and analyze QC materials to verify sensor performance after removing a clot.

If there is no obstruction, perform a wash. Observe the fluid as it moves through the system for sufficient wash flow, wash segments, and no leaks at sample port.

Check for cracks or leaks in the sample tubing. If necessary, replace the sample tubing as described in *Replacing the Sample Tubing* in Section 3.

Check the measurement module for leaks. Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Check the sample pump tubing for leaks, flattened areas, or other signs of wear. If necessary, replace the tubing as described in *Replacing the Pump Tubing* in Section 3.

Perform the Fluid Detector Test as described in *Fluid Detector Test*, page 4-66.

Perform the Pump Functions Test as described in *Pump Functions Test*, page 4-58.

If the D code reappears, contact your Service Representative.

D14 No Sample Detected at FD2 D14

Problem

Fluid detector 2 (FD2) does not detect the sample during the predefined time limit.

Solutions

Check the sample position in the measurement module.

If the sample is . . .	Then . . .
not positioned in the measurement module	1. Perform a wash. 2. Repeat the analysis and observe whether the sample moves past the measurement module without stopping. 3. If the sample moves past the measurement module without stopping, perform the Fluid Detector Test, page 4-66. 4. If the sample does not enter the measurement module, continue with the solutions to remove obstructions.
present in the measurement module	1. Perform a wash and observe the sample path for obstructions. 2. If you see obstructions, continue with the solutions to remove obstructions.

Check the measurement module for obstructions and remove them as described in *Removing Obstructions from the Measurement Module*, page 4-82.

Check the sample entry components for obstructions and remove them as described in *Removing Obstructions from the Sample Entry Components*, page 4-79.

Ensure that O-rings are in place on the sensors and that the sensors are aligned correctly as described in *Removing and Checking the Sensors* on page 4-65.

Perform the Fluid Detector Test as described in *Fluid Detector Test,* page 4-66.

Perform the Pump Functions Test as described in *Pump Functions Test*, page 4-58.

If the D code reappears, contact your Service Representative.

D19 D19 Fluid Detector Error:

Problem

Fluid detector millivolt (mV) reading is beyond predefined limits.

Qualifiers: FD1 FD1A FD2

Solutions

Check the sample path in the measurement module for obstructions or leaks. Ensure that O-rings are in place on the sensors and that the sensors are aligned correctly as described in *Removing and Checking the Sensors* on page 4-65.

If you see obstructions, remove them as described in *Removing Obstructions from the Measurement Module*, page 4-82.

Perform the Fluid Detector Test as described in *Fluid Detector Test*, page 4-66.

Deproteinize the sample path as described in *Deproteinizing the Sample Path* in Section 3, and repeat the Fluid Detector Test.

If the D code reappears, contact your Service Representative.

D19 Fluid Detector Error: D19

Problem

Fluid detector millivolt (mV) reading is beyond predefined limits.

Qualifiers: FD3 FD4

Solutions

Perform a wash. Observe the fluid as it moves through the system for sufficient wash flow, wash segments, and no leaks at the sample port.

Perform the Fluid Detector Test as described on page 4-66.

If the D code reappears, contact your Service Representative.

D19 D19 Fluid Detector Error:

Problem

Fluid detector millivolt (mV) reading is beyond predefined limits.

Qualifier: FD5

Solutions

Check the CO-ox sample path for obstructions. If you see any obstructions, remove them as described in *Removing Obstructions from the CO-ox Sample Path*, page 4-87.

Check the sample tubing that goes through FD5 for cracks, leaks, and discoloration. If you see cracks or leaks, replace the tubing as described in *Replacing the CO-ox Sample Tubing* in Section 3.

Perform the Fluid Detector Test as described in *Fluid Detector Test*, page 4-66.

Deproteinize the sample path as described in *Deproteinizing the Sample Path* in Section 3 and repeat the Fluid Detector Test.

If the D code reappears, contact your Service Representative.

D21 Processing Error: D21

Problem

An internal communication problem between the system processors has occurred.

Qualifiers: 1 3

Solutions

Qualifier	Procedure
1	Shut the system down and restart as described in *Shutting Down and Restarting the System* in Section 5.
3	Disconnect the CO-ox sample path as described in *Disconnecting the CO-ox Sample Path*, page 4-92. You can continue to analyze samples on the base model. Check that the communications cable connecting the CO-ox module to the base model is installed correctly. Shut the system down and restart as described in *Shutting Down and Restarting the System* in Section 5.

If the D code reappears, contact your Service Representative.

D22 D22 Barometric Pressure Error

Problem

The barometer detects atmospheric pressure beyond predefined limits.

Solutions

Check that the system barometer is functioning properly:

Menu Code 3 2

1. From the Menu screen, select **3 Troubleshooting** and press **Enter**.
2. Select **2 Temp/pAtm** and press **Enter**.
3. Press **Start Test**.
4. Check the screen to verify whether the atmospheric pressure (*p*Atm) is within the range of 400 to 825 mm Hg (53 to 110 kPa) and that the reading is stable.
5. Compare the atmospheric pressure displayed to the barometer in your laboratory to verify its accuracy.
6. Press **Stop Test**.
7. Press **Exit Test**.

If the reading is stable but does not match the barometer in your laboratory, calibrate the barometer:

Menu Code 1 8

8. From the Menu screen, select **1 Calibration** and press **Enter**.
9. Select **8 Barometer** and press **Enter**.
10. Type the correct atmospheric pressure and press **Enter**.
11. Press **Done**.
12. Perform a two-point calibration.

If the D code reappears, contact your Service Representative.

D23 Rgt Manifold: No (Qualifier) D23

Problem

Fluid detector 3 (FD3), fluid detector 4 (FD4), or both detectors do not detect reagent.

Qualifiers: 7.3 6.8 Wash C1/C2 Cal G/L

Solutions

For the 7.382 Buffer, 6.838 Buffer, Wash G/L Zero and Cal G/L reagents, check the expiration dates and the levels. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents as described in Section 3.

Menu Code

3 1 1

If the D23 . . .	Then . . .
disappears	perform a two-point calibration.
appears	perform the Fluidics Functions Test as described on page 4-56 for the appropriate reagent.

For the C1/C2 reagent, check the expiration date and level. Ensure that the reagent bottle is installed properly and in the correct location. If the C1/C2 has expired, is low, or is incorrectly installed, replace it. Prime the system.

Perform the Fluidics Functions Test as described in *Fluidics Functions Test,* page 4-56. If the D23 disappears, perform an Auto Clean as described in *Performing the Automatic Clean Sequence* in Section 3.

Check the reagent fittings for obstructions and clean the fittings as described in *Cleaning the Reagent Fittings* in Section 3.

Perform the Pump Flow Rate Test as described on page 4-57.

Perform the Valves Test as described on page 4-62 to verify that the 6.8, 7.3, Glu/Lac, Clean, and Vent valves are working.

Perform the Fluid Detector Test as described on page 4-66.

If the D code reappears, contact your Service Representative.

D24 D24 Meas Module: No (Qualifier)

Problem

Fluid detector 1 (FD1), fluid detector 2 (FD2), or both detectors do not detect fluid during a one-point or a two-point calibration.

Qualifiers: 7.3 6.8 Wash Cal G/L

Solutions

NOTE: If a D23 code also exists, correct that problem first, then correct the D24.

Check for cracks or leaks in the sample tubing.

Replace the sample tubing, if necessary, as described in *Replacing the Sample Tubing* in Section 3. Perform the Fluidics Functions Test as described in *Fluidics Functions Test*, page 4-56.

Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described as described in *Removing and Checking the Sensors* on page 4-65.

Check the expiration dates and the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagents, prime the system, and perform the Fluidics Functions Test as described on page 4-56.

Deproteinize the sample path as described in *Deproteinizing the Sample Path* in Section 3.

Perform the Fluid Detector Test as described in *Fluid Detector Test,* page 4-66.

Perform the Fluidics Functions Test as described in *Fluidics Functions Test,* page 4-56. If the D24 code disappears, perform a two-point calibration.

If the D code reappears, contact your Service Representative.

D29 Insufficient Wash Flow D29

Problem

The wash did not completely clean the sample path due to low volume or poorly segmented flow.

Solutions

NOTE: If a D23 or D24 code also exists, correct these problems first, then correct the D29.

Perform a wash.

Ensure that the bottle is installed properly. Check the level of Wash/Zero reagent. If the level is low, replace the reagent as described in *Replacing the Reagent Bottles* in Section 3.

Check for cracks or leaks in the sample tubing. If you find cracks or leaks, replace the sample tubing, as described in *Replacing the Sample Tubing* in Section 3.

Check the sample entry components for obstructions and remove them as described in *Removing Obstructions from the Sample Entry Components*, page 4-79.

Check the measurement module for leaks. Check that the sensors are installed in the correct order and are aligned, the O-rings are in place, and the spring-loaded latch is closed as described as described in *Removing and Checking the Sensors* on page 4-65.

If you see obstructions, remove them as described in *Removing Obstructions from the Measurement Module*, page 4-82.

Perform the *Valves Test* as described on page 4-62 to verify that the wash, diverter, vent, and wash bypass valves are functioning.

Perform the *Pump Functions Test* as described on page 4-58.

Check the pump tubing for leaks, flattened areas, or other signs of wear. If necessary, replace the tubing as described in *Replacing the Pump Tubing* in Section 3.

If the D code reappears, contact your Service Representative.

D33 D33 Probe Position Error

Problem

The probe detector cannot determine the position of the sample probe.

Solutions

Check to see if the probe is bent. If the probe is bent replace it as described in *Replacing the Sample Probe* in Section 3.

Check the sample port, the probe mount, and the capillary seal for obstructions, and ensure that the capillary seal is installed correctly. If obstructions are present:

1. Remove obstructions and reposition the capillary seal as described in *Removing Obstructions from the Sample Entry Components,* page 4-79.
2. Clean the sample probe with a lint-free tissue moistened with a 10% solution of household bleach, and rinse with reagent water.

   NOTE: Undiluted household bleach is 5.25% sodium hypochlorite.

Perform the *Sample Entry Test* as described on page 4-67.

Remove the sample probe and repeat the Sample Entry Test.

If the screen indicates that the probe is working properly, install a new sample probe as described in *Replacing the Sample Probe* in Section 3.

If the D code reappears, contact your Service Representative.

D35 Electronics Error: D35

Problem

The system detects an error in the electronics system.

Qualifiers: 1 2 4 5 6 7 8 9 10 11 12 13

Solutions

Qualifier	Procedure
1, 2, 4, 5, 8, 9, 11	perform the Measurement Test as described on page 4-70. If the measurement test does not remove the D35, shut the system down and restart it as described in *Shutting Down and Restarting the System* in Section 5.
6 or 7	shut down and restart the system as described in *Shutting Down and Restarting the System* in Section 5.
10	check the temperature control as described in *Temperature/pAtm Test*, page 4-69.
12	perform the Valves Test as described on page 4-62.
13	perform the Pump Functions Test as described on page 4-58.

If the D code reappears, contact your Service Representative.

D38 D38 Temperature Error:

Problem

The system detects an error in the temperature control system.

Qualifiers:1 2 3 4 5 6 7 8 9 10 11

Every 15 minutes, the system enables the temperature control and reevaluates the error condition. If the problem that caused the condition has been corrected, the system clears the D38 condition automatically. If the problem has not been corrected, it displays the D38 condition code again.

Solutions

Check that the measurement module door is closed tightly.

Check that the sample ground/temperature sensor is installed correctly. If the sensor is not correctly installed, remove and install it as described in *Cleaning the Sample Ground/Temperature Sensor* in Section 3.

Check that the location of the system meets the specifications for ambient operating temperatures as described in Appendix H, *Installation*.

Check the air filter to ensure that the air vent is not obstructed. If the air filter is obstructed or dirty, replace the air filter as described in *Replacing the Air Filter* in Section 3.

Check that the fan is operating.

Perform the Temperature/*p*Atm Test as described in *Temperature/*p*Atm Test*, page 4-69.

If the D code reappears, contact your Service Representative.

Glu

D50 Glucose Sensor Error D50

Problem

The system detects an open connection in the glucose biosensor.

Solutions

Check that the biosensor is installed correctly with the contacts aligned, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Check the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents are low or are incorrectly installed, replace the affected reagents, and perform a two-point calibration.

If the biosensor has been on the system less than one day, then perform three two-point calibrations.

Replace the biosensor as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.

If the D code reappears, contact your Service Representative.

D51 Lac

D51 Lactate Sensor Error

Problem

The system detects an open connection in the lactate biosensor.

Solutions

Check that the biosensor is installed correctly with the contacts aligned, and the spring-loaded latch is closed as described in *Removing and Checking the Sensors* on page 4-65.

Check the levels of the reagents. Ensure that the reagent bottles are installed properly and in the correct location. If reagents are low or are incorrectly installed, replace the affected reagents, and perform a two-point calibration.

If the biosensor has been on the system less than one day, then perform three two-point calibrations.

Replace the biosensor as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.

If the D code reappears, contact your Service Representative.

D60 Port <port> Error: D60

Problem

The system detects a transmission error in port 1, 2, 3, or the bar code scanner port, which is caused by a faulty cable connection or by the failure of the communications electronics.

Qualifiers: 1 2 3 4 5

Solutions

Ensure that the cable is firmly connected to the 800 system and to the external device.

Inspect the cable for wear or crimps.

Perform the procedure to configure the 800 system for the port with the transmission error. Refer to *Configuring for External Devices* in Section 5.

Perform the External Loopback Test for the port where the error occurred as described in *External Loopback Test*, page 4-75.

If the External Loopback Test fails and the cable is firmly connected to the port, replace the interface cable.

Perform the External Loopback Test again to ensure that the system sends and receives the transmissions. If the D code appeared when the system was transmitting results to the external device connected to the port, you can recall the results and transmit them again. You can also recall and transmit results obtained while the port was not operating. Refer to *Recalling Patient Sample Data*, *Recalling QC Data*, or *Recalling Calibration Data* in Section 2.

If the D code reappears, contact your Service Representative.

D70 D70 Optics Error:

Problem

The system detects an error in the CO-ox optical measurement system.

Qualifiers: 2 3 4 7 9

Solutions

Qualifier	Procedures
2	Perform a pH/Lytes one-point calibration. Replace the 7.3 Buffer/CO-ox zero reagent. Check that the area around the sample chamber is free from lint or dust. Prime and perform a pH/Lytes one-point calibration. Clean the sample chamber as described in *Cleaning the Sample Chamber.* It is not necessary to remove or replace the sample chamber gasket.
3	Perform a pH/Lytes one-point calibration. Perform CO-ox Optics test. Clean the sample chamber as described in *Cleaning the Sample Chamber.* It is not necessary to remove or replace the sample chamber gasket.
4	Ensure the CO-ox cover is closed. Perform a pH/Lytes one-point calibration.
7	Ensure the CO-ox cover is closed.
9	Contact your Service Representative.

If the D code reappears, contact your Service Representative.

D71 No Sample Detected at FD5 D71

Problem

Fluid detector 5 (FD5) does not detect the sample during the predefined time limit.

Solutions

Ensure the sample volume is sufficient for the sample type.

Check the sample entry components for obstructions and the sample path for blood clots. Remove them as described in *Removing Obstructions from the Sample Entry Components,* page 4-79.

Check the CO-ox sample tubing for cracks or leaks. Replace the tubing, if necessary, as described in *Replacing the CO-ox Sample Tubing,* in Section 3.

If you move the tubing or unfasten the FD5 tube locking mechanism you must perform a manual wash to recalibrate the fluid detector.

Deproteinize the sample path as described in *Deproteinizing the Sensors,* in Section 3.

Perform a two-point calibration and analyze QC materials, as necessary, to verify CO-ox performance.

Perform the Fluidics Functions Test as described in *Fluidics Functions Test,* page 4-56.

If the D code reappears, contact your service representative.

D72 D72 No CO-ox Sample Detected

Problem

The CO-ox sample chamber does not detect the sample during the predefined time limit.

Solutions

Ensure the sample volume is sufficient for the sample type.

Ensure the sample is red.

Check the CO-ox sample path for leaks or cracks. If you find cracks or leaks, replace the tubing as described in *Replacing the CO-ox Sample Tubing* in Section 3.

Check the CO-ox sample path for obstructions. If you see any obstructions, remove obstructions as described in *Removing Obstructions from the CO-ox Sample Path*, page 4-87.

If the D code reappears, contact your Service Representative.

D75 Lamp Failure D75

Problem

The CO-ox module detects lamp levels that are inadequate for sample analysis.

Solutions

Perform the Lamp On/Off Test as described in *CO-ox Optics Test*, page 4-75.

Remove the lamp cover from the CO-ox module and visually verify that the lamp is on. If the lamp is not on, replace it as described in *Replacing the CO-ox Lamp* in Section 3.

Visually verify that light is passing through the CO-ox sample chamber.

If the D code reappears, contact your Service Representative.

D76 D76 CO-ox Electronics Error:

Problem

The system detects an error in the electronics system.

Qualifiers: 1 2 3 4 5 6 7 8 9 10 11 12

Solutions

If the qualifier is . . .	Then . . .
1, 2, 3, 5, 8, 11	perform the CO-ox Lamp On/Off test, and then perform a one-point calibration. Shut the system down and restart: **Menu Code** 7 3 1. From the Menu screen, select **7 System Utilities** and press **Enter**. 2. Select **3 Shutdown** and press **Enter**. 3. Press **Yes**. 4. Wait at least 1 minute and then disconnect the power cord from the power source. 5. Wait at least 10 seconds and then connect the power cord to the power source.
4, 7, 9, 12	shut the system down and restart.
6	check the temperature control as described in *Temperature/pAtm Test*, page 4-69. Shut the system down and restart.
10	perform the Pump Functions Test as described in *Pump Functions Test*, page 4-58.

If the D code reappears, contact your Service Representative.

If the qualifier is . . .	Then . . .
1	testing occurs at power-up initialization and before each zero and slope calibration. The ±12V is checked before and after every sample measurement. A GO pulse is sent to the CMB. PWRGOOD is polled to determine if the power supplies are within range. .
2	testing occurs at power-up initialization and before each zero and slope calibration. A GO pulse is sent to the CMB. A counter verifies if the CMB generates 256 interrupts on ADCRDY. Integration time and CMB DAC value is checked.
3	testing occurs at power-up initialization and before each zero and slope calibration. Ground input to the ADC on the CMB is selected. A GO pulse is issued sent to the CMB and the resulting 256 values are averaged. An error is reported if the average value is outside the range $7F00_H$ to $80FF_H$.
4	testing occurs only at power-up initialization. The DAC value $016F_H$ is loaded. A dark measurement is initiated, the DAC is loaded with $05D0_H$, and another dark measurement is taken. The difference in ADC counts between the two measurements is to be 32,768 ±200 counts.
5	testing occurs at power-up initialization and before each zero and slope calibration. Ground is selected as the ADC input. A GO pulse is issued. The resulting 256 values are collected and the SD computed. An error is reported if SD is greater than 3.30 ADC counts.
6	testing occurs at power-up initialization and any time a heater control error is detected. This tests the integral non-linearity of the DAC. The DAC is alternately set to zero, mid-, and full scale. The output is read at each level. The value at each level must be within 100 mV after subtracting the offset of the GPADC (Refer to qualifier 11.): • Program 0 value into the DAC and read 0 ±100 mV. • Program 2047 into the DAC and read 2500 ±100 mV. • Program 4095 into the DAC and read 5000 ±100 mV.

(Continued)

If the qualifier is . . .	Then . . .
7	testing occurs at power-up initialization. Communications between the microstepper controller and the CPB are monitored for the response time to a command from the microstepper controller. The test steps are: • Reset the microstepper controller. • Enable microstepper controller. • Wait 100 µS for a response from the controller. If no response, the controller is not operating correctly.
8	testing is performed on a clean, sample chamber filled with bubble-free 7.3 Buffer/CO-ox Zero solution. During subsequent zeros the integration time is checked and readjusted (zero occurs during any 1-point calibration, except metabolite). If necessary, the lamp voltage or intensity is adjusted. Full calibration occurs during system initialization at start up. Testing also occurs during every sample, slope, or zero measurement.
9	testing occurs at power-up initialization by reading +12V and –12V with the general purpose ADC. The ±12V values are scaled to ±3.0V before going into the ADC. The ADC reading is to be +3.0V ±3% and –3.0V ±3%, respectively.
10	testing occurs at start up and during the CO-ox pump MIT (Pump MIT selects CO-ox). This test checks for current flow through the windings. A failure indicates that the motor driver electronics are malfunctioning or that the motor is disconnected. A MTR_CLR signal is initiated prior to reading the MTR_STATUS bit, which clears the latch from prior motor function. A TTL 1 on the MTR_STATUS identifies current flow through the motor windings.
11	testing occurs each time the general purpose ADC is calibrated. The GPADC is calibrated at power-up initialization, and each zero and slope calibration. Setting the GPADC to signal return and averaging several A/D readings determines Offset. Offset is checked to be within the range 0 ±100 mV. Setting the channel to the DAC reference signal and averaging several A/D readings determines Gain. Gain is computed as 5000 mV /(gain – offset reading). The value of Gain is 1.00 ±0.01.
12	testing occurs at start up. This test checks the status of the 24V power supply by measuring the 24V supply with the general purpose ADC. The 24V feed to the ADC is scaled down to 3.0V. The ADC reading is to be 3.0V ±10%.

D77 CO-ox Temperature D77

Problem

The system detects an error in the temperature control system.

Every 15 minutes, the system enables the temperature control and reevaluates the error condition. If the problem that caused the condition has been corrected, the system automatically clears the D77 condition. If the problem has not been corrected, the system displays the D77 condition code again.

Solutions

Check that the ambient temperature of the laboratory is between 15 and 32°C.

Perform the Temperature/*p*Atm Test as described on page 4-69.

Shut down and restart the system from the Menu screen as described in *Shutting Down and Restarting the System* in Section 5.

If the D code reappears, contact your Service Representative.

D78 D78 CO-ox Module: No (Qualifier)

Problem

Fluid detector 5 (FD5), the CO-ox sample chamber, or both do not detect reagent.

Qualifiers: 7.3 Wash

Solutions

Check the expiration dates and levels of the 7.3/COox Zero and the Wash/Glu Zero. Ensure that the reagent bottles are installed properly and in the correct location. If reagents have expired, are low, or are incorrectly installed, replace the affected reagent. Perform a one-point calibration if the D78 disappears.

Ensure that the CO-ox sample path is connected to the base model. If the sample connector needs to be inverted, refer to *Disconnecting the CO-ox Sample Path*, page 4-92 for instructions.

Check the CO-ox sample path for obstructions. If you see any obstructions, remove obstructions as described in *Removing Obstructions from the CO-ox Sample Path*, page 4-87.

Check the CO-ox sample tubing for leaks or cracks. If you find cracks or leaks, replace the tubing as described in *Replacing the CO-ox Sample Tubing* in Section 3.

Check the gasket in the hemolyzer for cracks and that the gasket is seated correctly. If necessary, replace or reinstall the gasket as described in *Cleaning the Hemolyzer* in Section 3.

Check the CO-ox sample chamber for obstructions and that the gasket is seated correctly. If necessary, remove obstructions or reinstall the gasket as described in *Cleaning the CO-ox Sample Chamber* in Section 3.

Perform a one-point calibration.

Perform the Fluidics Functions Test for the appropriate reagent as described in *Fluidics Functions Test*, page 4-56.

Check the CO-ox pump tubing for leaks, flattened areas, or other signs of wear. Replace the tubing, if necessary, as described in *Replacing the CO-ox Pump Tubing* in Section 3.

Perform the Pump Functions Test as described in *Pump Functions Test*, page 4-58.

If the D code reappears, contact your Service Representative.

D79 D79 CO-ox Insufficient Wash Flow

Problem

The wash did not completely clean the CO-ox sample path due to low volume or poorly segmented flow.

Solutions

NOTE: If a D78 also exists, correct that problem first, then correct the D79.

Perform a wash.

Ensure that the Wash/Glu zero reagent bottle is installed properly. Check the level of reagent. If the level is low, replace the reagent as described in *Replacing the Reagent Bottles* in Section 3.

Check the CO-ox sample tubing for leaks or cracks. If necessary, replace the tubing as described in *Replacing the CO-ox Sample Tubing* in Section 3.

Check that the gaskets in the CO-ox sample chamber and hemolyzer are seated correctly. If necessary, reinstall either gasket as described in *Cleaning the CO-ox Sample Chamber* or *Cleaning the Hemolyzer* in Section 3.

Perform the valves diagnostic test to verify that the wash, diverter, vent, and wash bypass valves are functioning as described in *Valves Test*, page 4-62.

Perform the Pump Functions Test as described in *Pump Functions Test*, page 4-58.

Check the CO-ox pump tubing for leaks, flattened areas, or other signs of wear. Replace the tubing, if necessary, as described in *Replacing the CO-ox Pump Tubing* in Section 3.

If the D code reappears, contact your Service Representative.

Using the Diagnostic Tests

This section describes how to use the 800 system diagnostic tests to check the functions of the system components. Access the tests from the Troubleshooting menu or by pressing **Troubleshooting** at the View Status screen. Table 4-2 describes the function of each test.

Table 4-2. 800 System Diagnostic Tests

Test	*Function*
Fluidics Functions	Tests the ability of the reagent components to deliver the reagents to the fluid detectors in the reagent manifold and the measurement module.
Pump Flow Rate	Tests the ability of the reagent pump to pump a specified amount of fluid in a specified period of time.
Pump Functions	Tests the ability of all pumps to turn on and off and lets you manually test the flow rates for these pumps.
Valves	Tests the solenoid valve electronics and the ability of the valves to open and close. The valves tested are 6.8, 7.3, foam, wash, vent, clean, bypass, cal gas, slope gas, glu/lac, and diverter.
Gas Flow Rates	Tests the ability of the Cal Gas and Slope Gas valves to control the flow of gases.
Fluid Detector	Tests the ability of the fluid detectors to detect the presence of fluids and to detect whether the fluids are clear or opaque.
Sample Entry	Tests the ability of the system to identify the position of the sample door and of the sample probe and to detect the type of sample device. This test can also calibrate the sample door.
Temperature/*p*Atm	Displays the temperature readings for the measurement module, the sample, the measurement module window, and the preheater. The test also displays the atmospheric pressure.
Measurement	Tests the measurement electronics by displaying sensor voltage and current output.
COox Optics	Tests the operation of the lamp on the CO-ox module and provides the integration time of the last one-point calibration.
External Loopback	Tests the communication between the user-interface processor, the serial ports, and the external cable connected to each port.

(Continued)

Test	Function
Roll Printer	Tests the ability of the roll printer to print all characters.
Bar Code Scanner	Tests the ability of the bar code scanner to read a test pattern.

Fluidics Functions Test

Use this procedure to test the ability of the reagent components to deliver reagents to the fluid detectors in the reagent manifold and the measurement module.

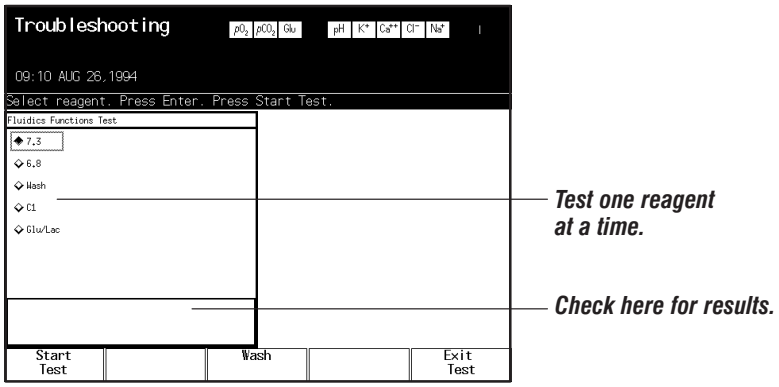
Menu Code

3 ***1*** ***1***

1. Access the Fluidics Functions Test screen from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **1 Fluidics Functions** and press **Enter**.

   The Fluidics Functions Test screen appears as shown in Figure 4-2 for an 860 system.

Figure 4-2. Fluidics Functions Test Screen



2. Select the reagent you want to test and press **Enter**.
3. Press **Start Test**.
4. Check the screen for the message, Fluidics functions acceptable, to verify that the system delivers the reagent to the fluid detectors.

5. Perform the appropriate action.

If you want to . . .	*Then . . .*
test another reagent	repeat steps 2 through 4.
return to the Menu screen	press **Exit Test**.

6. Press **Exit Menu**.

Pump Flow Rate Test

Use this procedure to test the flow rate of the reagent pump and to calibrate the reagent pump, if necessary.

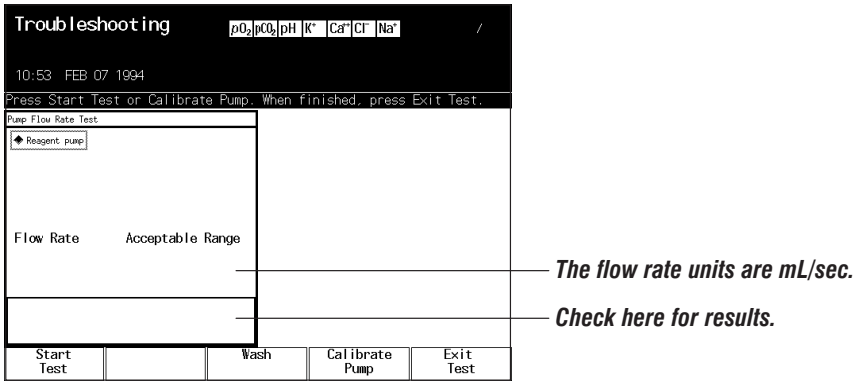
Menu Code

3 *1* *2*

1. Access the Pump Flow Rate Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **2 Pump Flow Rate** and press **Enter**.

   The Pump Flow Rate Test screen appears as shown in Figure 4-3.

Figure 4-3. Pump Flow Rate Test Screen



2. Press **Start Test**.

3. Check the screen for the message, Reagent pump flow rate acceptable, to verify that the flow rate is within the acceptable range.

If the flow rate is . . .	*Then . . .*
acceptable	press **Exit Test**.
unacceptable	a. Press **Calibrate Pump**. b. Check the screen for the message, Pump calibration complete. c. Press **Exit Test**.

4. Press **Exit Menu**.

Pump Functions Test

Use this procedure to test the ability of the reagent, sample, and waste pumps to turn on and off and to manually test the flow rates for the reagent, sample, waste, and CO-ox pumps. The flow rate is the amount of fluid the pumps can pump in a specified time.

Materials required for the manual pump flow rate test:

- stopwatch
- 10 mL graduated cylinder
- small container of reagent water
- 2 small two-way connectors
- 2 pieces of test tubing, each approximately 30 cm (10 inches) long with approximately 0.15 cm (0.060 inches) inner diameter

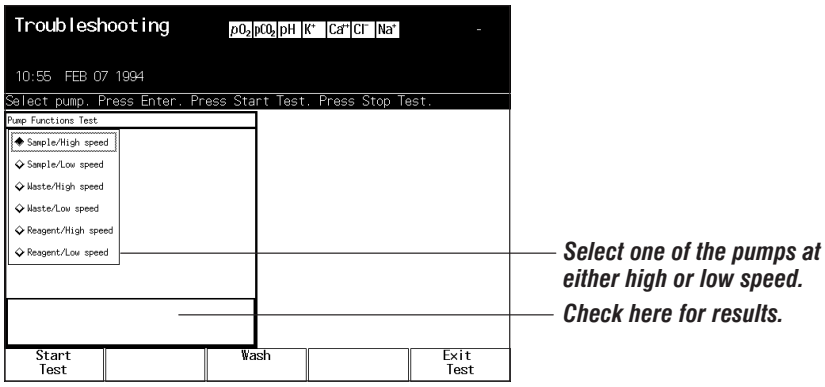
Menu Code

3 1 3

1. Access the Pump Functions Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **3 Pump Functions** and press **Enter**.

   The Pump Functions Test screen appears as shown in Figure 4-4.

Figure 4-4. Pump Functions Test Screen



2. Test the pump electronics:
   a. Select the pump and speed to test and press **Enter**.
   b. Press **Start Test**.

      The pump turns on.

   NOTE: When you select the reagent pump, the waste pump also turns on.

   c. Check the screen for the message, Pump current acceptable, to verify that the pump electronics are functioning correctly.
   d. Press **Stop Test**.
3. Perform the appropriate action.

If you want to . . .	*Then . . .*
measure the flow rate of the reagent, sample, or waste pump	continue with step 4.
return to the Menu screen	continue with step 11.

4. Install the test tubing on the reagent, sample, or waste pump as shown in Figure 4-5:

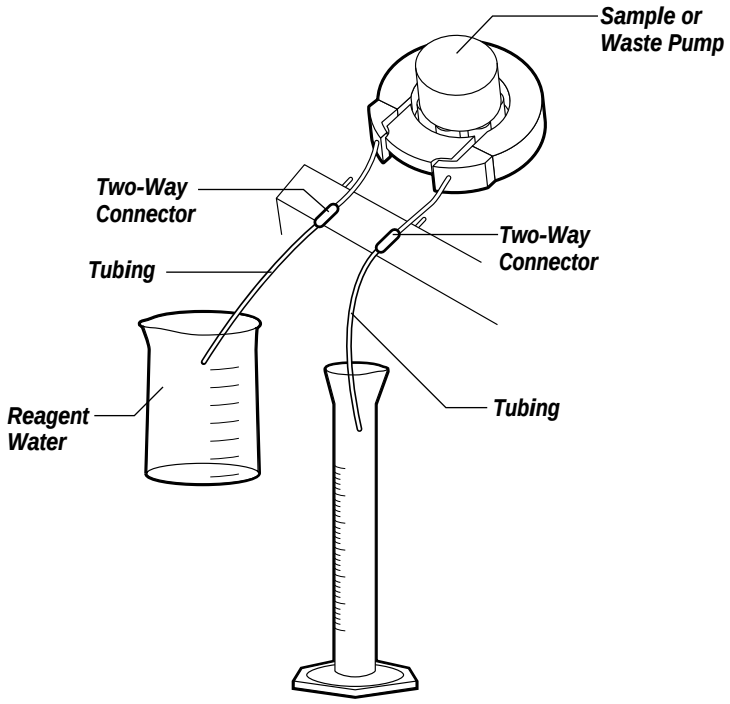
   NOTE: The reagent pump turns counterclockwise and the sample and waste pumps turn clockwise.

   a. Disconnect the pump tubing from the connectors for the pump.
   b. Attach one piece of test tubing to a two-way connector, attach the connector to the inlet tubing for the appropriate pump, and place the test tubing in a beaker of reagent water.

c. Attach another piece of test tubing to a two-way connector, attach the connector to the outlet tubing for the appropriate pump, and place the test tubing in the graduated cylinder.

If you want to . . .	*Then connect the test tubing . . .*
test the reagent pump	a. to the pump inlet tubing connected to right position 1 b. and to the outlet tubing connected to left position 1.
test the sample pump	a. to the pump inlet tubing connected to left position 4 b. and to the outlet tubing connected to right position 4.
test the waste pump	a. to the pump inlet tubing connected to left position 5 b. and to the outlet tubing connected to right position 5.

Figure 4-5. Measuring the Flow Rate for the Sample or Waste Pump



5. Install the test tubing on the CO-ox pump:

NOTE: The CO-ox pump turns clockwise.

a. Disconnect the sample and waste tubing from the pump tubing.

b. Attach one piece of test tubing to sample tubing connector on the CO-ox pump tubing, and place the test tubing in a beaker of reagent water.

c. Attach another piece of test tubing to the waste tubing connector on the CO-ox pump tubing, and place the test tubing in the graduated cylinder.

6. Select the pump and speed to test and press **Enter**.
7. Prime the tubing:
   a. Press **Start Test**.
   b. Allow reagent water to flow through all the tubing.
   c. Press **Stop Test**.
   d. Empty the graduated cylinder.
8. Test the pump flow rate for 1 minute:
   a. Place the outlet tubing in the graduated cylinder.
   b. Press **Start Test** and simultaneously start timing with a stopwatch.
   c. Collect fluid for exactly 1 minute.
   d. Press **Stop Test**.
   e. Compare the volume of collected fluid to the expected ranges.

Pump	*Volume at low speed*	*Volume at high speed*
reagent	1.51 – 1.85 mL/min	5.94 – 7.26 mL/min
sample	1.51 – 1.85 mL/min	5.94 – 7.26 mL/min
waste	1.51 – 1.85 mL/min	7.02 – 8.58 mL/min
CO-ox	0.27 – 0.33 mL/min	5.94 – 7.26 mL/min

9. If the measured volume is not acceptable, the pump tubing may be worn or damaged, the roller cage or shaft may be dirty, or the pump speed may require calibration.
10. Perform the appropriate action.

If you want to . . .	*Then . . .*
measure the flow rate of the same pump at a different speed	a. Empty the graduated cylinder. b. Select the pump and speed to test and press **Enter**. c. Repeat steps 7 and 8.
measure the flow rate of a different pump or return to the Menu screen	continue with step 11.

11. Reinstall the reagent, sample, or waste pump tubing:
    a. Disconnect the test tubing and the two-way connectors from the pump tubing.
    b. Reinstall the pump tubing:
       - reagent pump tubing to the connectors at position 1
       - sample pump tubing to the connectors at position 4
       - waste pump tubing to the connectors at position 5
12. Reinstall the CO-ox tubing:
    a. Disconnect the test tubing from the pump tubing.
    b. Reconnect the sample tubing to the sample tubing connector on the pump.
    c. Reconnect the waste tubing to the waste tubing connector on the pump.
13. Perform the appropriate action.

If you want to . . .	*Then . . .*
measure the flow rate of a different pump	repeat steps 4 through 9.
return to the Menu screen	a. Press **Exit Test**. The Menu screen appears. b. Press **Exit Menu**.

Procedural Notes

When you use the left arrow key to exit the Troubleshooting menu and enter the Main menu, the system performs a wash.

Valves Test

Use this procedure to test the solenoid valve electronics and to test the ability of the valves to open and close. You can test the following valves:

Valve	*Function*
6.8	controls the flow of 6.838 Buffer
7.3	controls the flow of 7.3/CO-ox Zero Buffer
Foam	controls the flow of Wash G/L Zero Reagent during the foam wash sequence
Wash	controls the flow of Wash G/L Zero Reagent

(Continued)

Valve	Function
Vent	controls the flow of ambient air into the manifold
Clean	controls the flow of Cleaning Solution
G/L	controls the flow of Cal G/L Reagent
Bypass	diverts the Wash G/L Zero Reagent in the reagent manifold when the foam wash valve is off, preventing a pressure buildup
Diverter	directs the flow of reagent into either the calibration passage or the wash passage of the sample port

If you want to test the Cal Gas or Slope Gas valves, refer to *Checking the Gas Flow*, page 4-64.

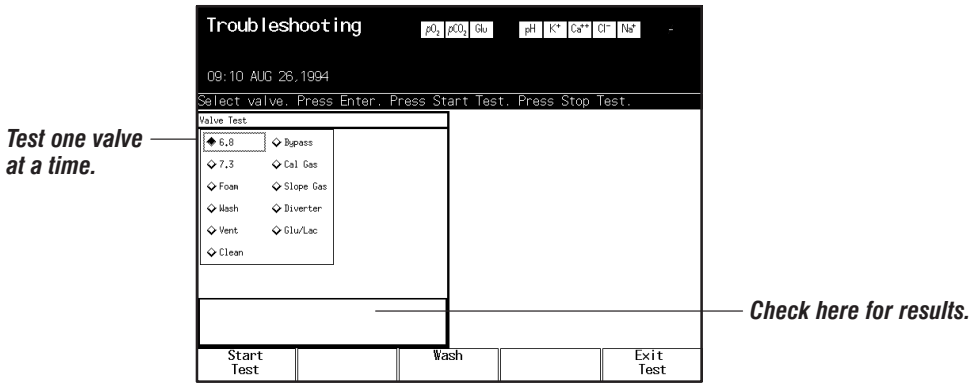
Menu Code

3 ***1*** ***4***

1. Access the Valves Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **4 Valves** and press **Enter**.

   The Valve Test screen appears as shown in Figure 4-6.

Figure 4-6. Valve Test Screen on an 860



2. Select the valve you want to test and press **Enter**.
3. Press **Start Test**.

   Listen for a distinctive click, which indicates the opening of the valve, and check the screen for the message, Valve energized, to verify that the valve is operating correctly.
4. Press **Stop Test**.

   Listen for a distinctive click, which indicates the closing of the valve.

5. Perform the appropriate action.

If you want to . . .	*Then . . .*
test another valve	repeat steps 2 through 4.
return to the Menu screen	press **Exit Test**.

6. Press **Exit Menu**.

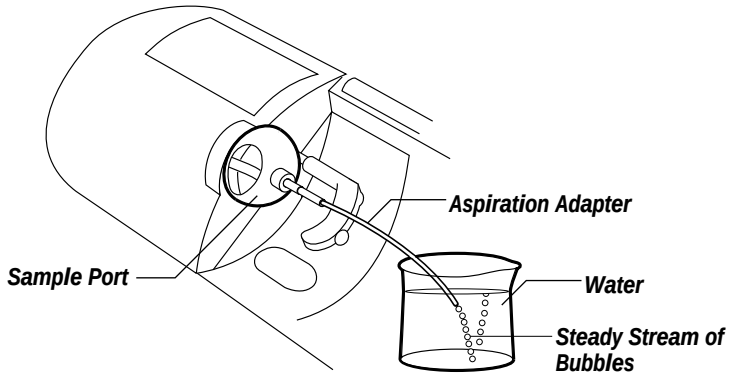
Procedural Notes

When you use the left arrow key to exit the Troubleshooting menu and enter the Main menu, the system performs a wash.

Checking the Gas Flow

Use this procedure to test the flow of Cal Gas and Slope Gas. Refer to Figure 4-7 as you perform this procedure.

Figure 4-7. Checking the Gas Flow



1. Fill a small container with reagent water.

Menu Code

3 1 4

2. Access the Valves Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **4 Valves** and press **Enter**.
3. Check the flow of Cal Gas:
   a. Select **Cal Gas** and press **Enter**.
   b. Push down the sample door halfway open, insert an aspiration adapter into the sample port, and immerse the other end in the water.
   c. Press **Start Test**.

   Ensure that a steady stream of bubbles flows from the aspiration adapter.

d. Press **Stop Test**.

Ensure that the bubbles stop flowing from the adapter.

4. Check the flow of Slope Gas:
   a. Select **Slope Gas** and press **Enter**.
   b. If required, push down the sample door halfway open, insert an aspiration adapter into the sample port, and immerse the other end in the water.
   c. Press **Start Test**.

      Ensure that a steady stream of bubbles flows from the aspiration adapter.
   d. Press **Stop Test**.

      Ensure that the bubbles stop flowing from the adapter.
5. Remove the aspiration adapter and manually close the sample door.
6. Press **Exit Test**.
7. Press **Exit Menu**.

Procedural Notes

When you use the left arrow key to exit the Troubleshooting menu and enter the Main menu, the system performs a wash.

Removing and Checking the Sensors

Menu Code

2 *7*

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

CAUTION: Touch the inner surface of the module frame to discharge static buildup before removing or returning sensors.

2. Remove the sensors.
3. Check that the O-rings are in place.
4. Install the sensors in their correct positions by aligning the top of the sensor with the sensor contact and snapping the body of the sensor into place.
5. Close the measurement module door.
6. Press **Continue** and allow the system to warm up.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
7. Press **Yes** to perform a two-point calibration.

Fluid Detector Test

Use this procedure to test the ability of the fluid detectors to detect the presence of fluids and to detect whether the fluids are clear or opaque. You can also test fluid detectors 1, 1A, and 2 with whole blood by inserting a sample device containing whole blood into the sample port.

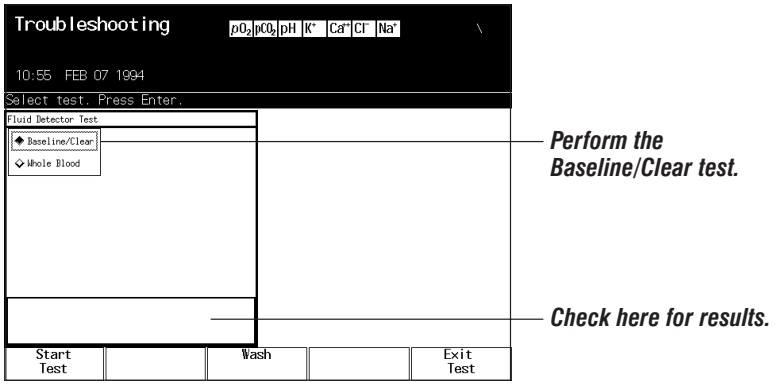
Menu Code

3 ***1*** ***5***

1. Access the Fluid Detector Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **5 Fluid Detector** and press **Enter**.

   The Fluid Detector Test screen appears as shown in Figure 4-8.

Figure 4-8. Fluid Detector Test Screen



2. Test the fluid detectors with clear fluid and air:
   a. Select **Baseline/Clear** and press **Enter**.
   b. Press **Start Test**.
   c. Check the screen for the message FD1, FD1A, FD2, FD3, FD4, FD5 acceptable to verify correct fluid detector function.
   d. Press **Exit Test**.
3. Perform the appropriate action.

If . . .	***Then . . .***
the fluid detector failed the Baseline test	continue with step 6.
you want to test whole blood	continue with step 4.
you want to return to the Menu screen	continue with step 6.

4. Test the fluid detectors with whole blood:
   a. Select **Whole Blood** and press **Enter**.
   b. Insert a sample device containing a whole blood sample into the sample port.
   c. Press **Start Test**.
   d. Remove the sample device when prompted.
   e. Check the screen for the message, FD1, FD1A, FD2, FD5 acceptable, to verify correct fluid detector function.

   The system automatically performs a full wash sequence.
5. Repeat step 4 if you want to test the fluid detectors with another type of fluid.
6. Press **Exit Test**.
7. Press **Exit Menu**.

Sample Entry Test

Use this procedure to test the ability of the system to:

- move the sample door and the sample probe
- identify the position of the sample door and the sample probe
- detect the type of sample device
- detect an obstruction
- calibrate the sample door to various types of sample devices

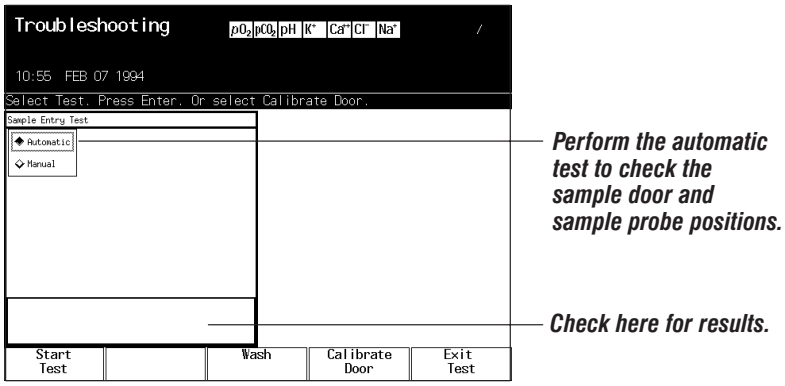
Menu Code

3 ***1*** ***6***

1. Access the Sample Entry Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **6 Sample Entry** and press **Enter**.

   The Sample Entry Test screen appears as shown in Figure 4-9.

Figure 4-9. Sample Entry Test Screen



2. Test the positions of the sample door and the sample probe:
   a. Select **Automatic** and press **Enter**.
   b. Press **Start Test**.
   c. Check the screen for the message, Sample entry module acceptable, to verify that the sample door and sample probe function correctly.
   d. Press **Exit Test**.
3. Test the ability of the system to recognize the sample device:
   a. Select **Manual** and press **Enter**.
   b. Insert a sample device, with the plunger pulled back, into the sample port when prompted.
   c. Press **Start Test**.
   d. Remove the sample device when prompted.
   e. Check the screen to verify that the system correctly identifies the size and the type of the sample device.
   f. Press **Exit Test**.
4. Test the ability of the sample probe to detect obstructions:
   a. Select **Manual** and press **Enter**.
   b. Push in completely the plunger of a syringe and insert the syringe into the sample port when prompted.
   c. Press **Start Test**.
   d. Remove the syringe when prompted.
   e. Check the screen to verify that the sample probe detects an obstruction and identifies the size of the sample device.

5. If the system does not correctly recognize the sample device, calibrate the sample door:
   a. Press **Calibrate Door**.
   b. Insert the door calibration gauge. Use a Bayer Diagnostics 1 mL syringe size.
   c. Press **Start Test**.
   d. Remove the sample device when prompted.
   e. Check the screen to verify that the sample door is calibrated.
6. Press **Exit Test** twice.

Temperature/pAtm Test

Use this procedure to test the temperature and barometer controls when the system generates a D38 or D22 code. If this test is successful, the D38 or D22 code is cleared from the status area. This test also displays the temperature readings for the measurement module, the sample path, the measurement module window, the preheater, and the barometric pressure.

NOTE: The 37°C temperature set point is NIST traceable.

Menu Code
3 ***2***

1. Access the Temperature/*p*Atm Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **2 Temp/pAtm** and press **Enter**.
2. Press **Start Test**.
3. Perform the appropriate action.

If you see a . . .	*Then . . .*
D38 code	a. Check the screen for the message, Temperature control system on. b. Press **Stop Test**. c. If the temperature control system is off, press **Reset Control**. d. Continue with step 4.
D22 code	a. Press **Stop Test**. b. Look at the status area to see if the D22 code has disappeared. c. Continue with step 5.

4. Perform the appropriate action.

If you see the . . .	*Then . . .*
Temperature control system on message	a. Press **Stop Test**. b. Look at the status area to see if the D38 code has disappeared. c. Allow the system to reach operating temperature.
Temperature control system off message	the system cannot reset the temperature control system.

5. Press **Exit Test**.

Measurement Test

Use this procedure to test the measurement electronics. You can:

- print stored signals from the last successful two-point calibration
- test the sensor circuit without a sensor and with a test/blank sensor

Printing Stored Signals

Menu Code

3 *3* *1*

1. Access the Measurement Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **3 Measurement** and press **Enter**.
   c. Select **1 Measurement** and press **Enter**.
2. Press **Print Last Cal Mv**.
3. Compare the results on the report to the expected values in the following tables.

Sensor	*Cal Signal Expected Value*	*End Time, (sec) Expected Value*
pH	194.0 to 406.0 mV	20 to 90
pCO_2	–216.0 to +106.0 mV	25 to 90
pO_2	–0.129 to +2.071 nA	5 to 90
Na^+	29.0 to 131.0 mV	15 to 90

(Continued)

Sensor	Cal Signal Expected Value	End Time, (sec) Expected Value
K^+	29.0 to 126.0 mV	15 to 90
Cl^-	29.0 to 126.0 mV	15 to 90
Ca^{++}	29.0 to 126.0 mV	20 to 90
Glu I	–5.35 to +16.45 nA	
Glu A	–5.35 to +16.45 nA	45
Lac I	–5.35 to +16.45 nA	
Lac A	–5.35 to +16.45 nA	45

Sensor	Slope Signal Expected Value	End Time, (sec) Expected Value	Sensor Slope Expected Value
pH	217.1 to 443.3 mV	20 to 90	42.5 to 68.5 mV/Dec
pCO_2	–203.2 to +126.6 mV	25 to 90	42.5 to 68.5 mV/Dec
pO_2	–0.300 to +0.360 nA	5 to 90	0.002 to 0.020 nA/mmHg
Na^+	35.2 to 141.0 mV	15 to 90	42.5 to 68.5 mV/Dec
K^+	41.8 to 146.6 mV	15 to 90	42.5 to 68.5 mV/Dec
Ca^{++}	34.7 to 137.1 mV	20 to 90	19.0 to 36.8 mV/Dec
Cl^-	18.4 to 121.3 mV	15 to 90	–30.0 to –68.5 mV/Dec
Glu I	–5.35 to 16.45 nA		
Glu A	1.85 to 88.45 nA	12 to 90	0.040 to 0.400 nA/mg/dL
Lac I	–5.35 to 16.45 nA		
Lac A	–3.35 to 42.45 nA	12 to 90	1.00 to 13.00 nA/mmol/L

4. Press **Exit Test**.

Testing a Sensor Circuit

Tools and Supplies

- TB1, pO_2/pCO_2 Test/Blank Sensor
- TB2, pH/Na^+ Test/Blank Sensor
- TB3, $K^+/Ca^{++}/Cl^-$ Test/Blank Sensor
- TB4, Glucose/Lactate Test/Blank Sensor

Menu Code 3 3

1. Access the Measurement Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **3 Measurement** and press **Enter**.

CAUTION: Touch the inner surface of the module frame to discharge static buildup before removing or returning sensors.

2. Remove the appropriate sensors:
   a. Open the measurement module door.
   b. If you are testing a pH or ISE sensor circuit, remove the reference sensor.
   c. Remove the measurement sensor.
   d. Close the measurement module door.
3. Perform the Measurement Test without a sensor:
   a. Press **Start Test**.
   b. Take a reading of the actual sensor output signal.
   c. Compare the result to the expected value.

860 **NOTE:** Two values are reported for the glucose and lactate biosensors.

Sensor Circuit	Expected Value
pCO_2	–6.000 to +6.000 mV
pO_2	20.607 to 16.191 nA
pH, Na^+, K^+, Ca^{++}, or Cl^-	–6.000 to +6.000 mV
860 Glu I	–5.348 to +5.348 nA
860 Glu A	25.252 to 54.748 nA
Lac I	–5.348 to +5.348 nA

(Continued)

Sensor Circuit	Expected Value
Lac A	17.602 to 42.398 nA
sample ground/temperature	36.840 to 37.373°C

d. Press **Stop Test**.

e. Perform the appropriate action.

If the result . . .	Then . . .
is within the expected value	continue with step 4.
is not within the expected value	the sensor circuit fails the test. Continue with step 6.

NOTE: The measurement test, which requires approximately 8 minutes to complete, can effectively evaluate measurement system failures.

4. Install a test/blank sensor:

   a. Open the measurement module door.

   b. Perform the appropriate action.

If you want to test the . . .	Then install the . . .
pO_2 or pCO_2 sensor circuit	TB1 test/blank sensor.
pH or Na^+ sensor circuit	TB2 test/blank sensor.
850 860 K^+, Ca^{++}, or Cl^- sensor circuit	TB3 test/blank sensor.
860 Glu biosensor circuit	TB4 test/blank sensor.
Lac biosensor circuit	TB4 test/blank sensor.

   c. Close the measurement module door.

5. Perform the Measurement Test:

   a. Press **Start Test**.

   b. Check the screen for a value of –250 to +250 mV for pCO_2 and –450 to +450 mV for pH and ISE. If required, remove and reinstall the test/blank sensor until the value is within this range.

   c. For all sensor circuits except pO_2, wait at least 4 minutes after closing the door.

d. Take a reading of the actual sensor output signal.

e. Wait 100 seconds, and take another reading.

value = (reading 1 – reading 2) / 100 seconds

f. Calculate the resulting value and then compare the resulting value to the expected value:

Sensor Circuit	*Expected Value*
pCO_2	–0.800 to +0.800 mV/s
pO_2	–0.300 to +0.300 nA
pH, Na^+, K^+, Ca^{++}, or Cl^-	–0.545 to +0.545 mV/s
860 Glu I, Glu A	–5.348 to +5.348 nA
Lac I, Lac A	–5.348 to +5.348 nA

g. Press **Stop Test**.

CAUTION: Touch the inner surface of the module frame to discharge static buildup before removing or returning sensors.

6. Reinstall the sensors:

a. Open the measurement module door.

b. Remove the test/blank sensor.

c. Reinstall the measurement sensor.

NOTE: If you want to test another sensor, repeat steps 4b through 6c.

d. Reinstall the reference sensor if you removed it.

e. Close the measurement module door.

CAUTION: Before you press **Exit Test**, replace all sensors to prevent fluid from spilling into the measurement module.

7. Press **Exit Test**.

Perform a two-point calibration to ensure optimum performance.

NOTE: If you encounter any difficulties when performing or interpreting the results of this test, contact your Service Representative for assistance.

CO-ox Optics Test

You can use this procedure to test the operation of the CO-ox lamp and to display the integration time for the last CO-ox zero calibration.

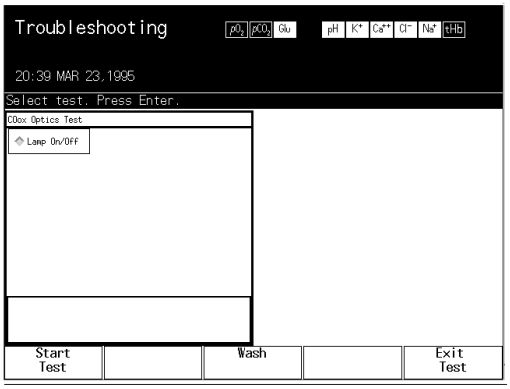
Menu Code

3 3 2

1. Access the CO-ox Optics Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **3 Measurement** and press **Enter**.
   c. Select **2 COox Optics** and press **Enter**.

   The CO-ox Optics Test screen appears as shown in Figure 4-10.

Figure 4-10. CO-ox Optics Test Screen



2. Press **Start Test**.
3. Check the screen for the message, Lamp test passed.

   NOTE: The system requires a one-point calibration to zero the CO-ox module when the lamp test is complete. The message, Calibration Overdue: COox Zero, is displayed when the test is run.

   The integration time for the zero calibration should be between 8,000 and 80,000 µsec.

4. Press **Exit Test**.

External Loopback Test

Use this procedure to test the communication between the user-interface processor, the serial ports, and the external cable connected to each port. The loopback connector and the cable matching connector are required for this test.

Menu Code

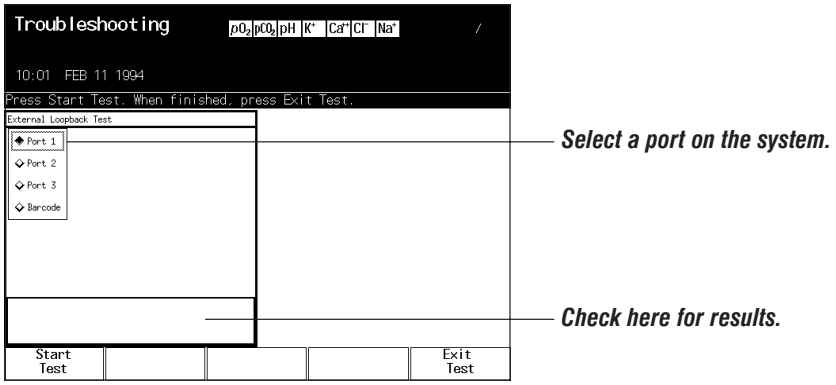
3 4

1. Access the External Loopback Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.

b. Select **4 Communications** and press **Enter**.

The External Loopback Test screen appears as shown in Figure 4-11.

Figure 4-11. External Loopback Test Screen



2. Select the appropriate port and press **Enter**.

   NOTE: Attach the loopback connector to the cable matching connector, if your cable requires one.

3. Attach the loopback connector as follows.

If you want to test . . .	*Then . . .*
the 800 system	a. Remove the cable from the port on the 800 system. b. Attach the loopback connector to the port.
the cable between the 800 system and the external device	a. Remove the cable from the port on the external device. b. Attach the loopback connector to the end of the cable.

4. Press **Start Test**.
5. Check the screen for the message, Port_acceptable, to verify that the port passes the test.
6. Remove the loopback connector and reconnect the external device to that port.
7. Press **Exit Test**.

Roll Printer Test

Use this procedure to test the ability of the roll printer to print all characters in the character set. Failure of the roll printer to print the entire character set indicates a problem with the printer assembly, the printer interface, or the printer assembly cables.

CAUTION: Do not attempt to print without paper in the printer. Damage to the printer can occur.

Menu Code 3 5

1. Access the Roll Printer Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **5 Roll Printer** and press **Enter**.
2. Press **Start Test**.
3. Check the printed test pattern to verify that the roll printer prints all characters clearly across the page.
4. If the test results are unacceptable, refer to *Cleaning the Roll Printer* in Section 3, and then repeat the roll printer test.
5. Press **Exit Test**.

Bar Code Scanner Test

Use this procedure to test the ability of the bar code scanner to read a test pattern.

Menu Code 3 6

1. Access the Bar Code Scanner Test from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **6 Barcode Scanner** and press **Enter**.
2. Scan the bar code scanner test pattern in Figure 4-12 with the bar code scanner.

Figure 4-12. Bar Code Scanner Test Pattern

3. Check the screen to verify that the characters are readable and that they correspond to the bar code in the test pattern.

   If the screen shows no characters, refer to *Troubleshooting Bar Codes*, page 4-109.

   If you successfully scan the bar code label in Figure 4-12 but you cannot successfully scan the bar code labels that your laboratory uses, use better quality bar code labels.
4. Press **Exit Test**.

Removing Obstructions from the Sample Entry Components

Use this procedure to remove obstructions from the sample entry components. Perform the steps in sequence until you locate and remove the obstructions.

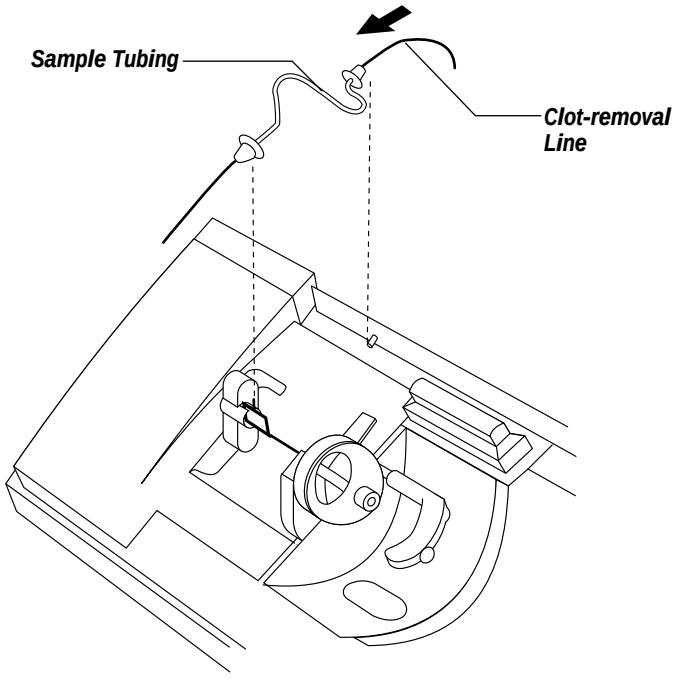
Menu Code
2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

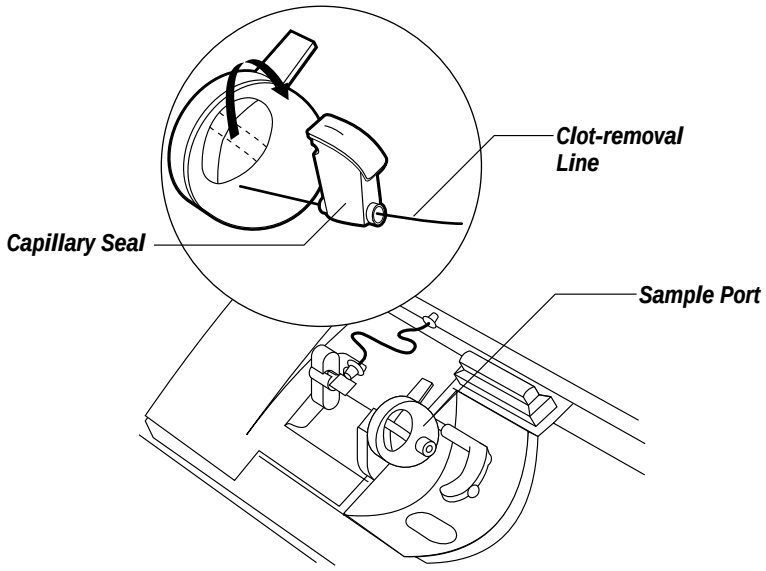
2. Remove obstructions from the sample entry area:
   a. Place a gauze pad in front of the sample port.
   b. Turn the sample pump counterclockwise until the obstruction is ejected onto the gauze pad.
3. Remove obstructions from the sample tubing:
   a. Inspect the sample tubing for obstructions.
   b. Remove the sample tubing.
   c. Push a 0.558 mm (0.022-inch) diameter clot-removal line through the sample tubing from back to front, opposite the direction of sample flow, as shown in Figure 4-13.
   d. Reinstall the sample tubing.

Figure 4-13. Removing Obstructions from the Sample Tubing



4. Remove obstructions from the sample probe using the clot-removal line from the probe clot removal kit:
   a. Disconnect the sample tubing from the sample probe.
   b. Push a 0.016-inch diameter clot-removal line through the sample probe until the line comes out of the sample port.
5. Remove obstructions from the capillary seal, as shown in Figure 4-14:
   a. Grasp the top of the capillary seal and pull it out of the sample port.
   b. Inspect the capillary seal for obstructions.
   c. Inspect the opening in the sample port for obstructions.
   d. Push a 0.558 mm (0.022-inch) diameter clot-removal line through the capillary seal, against the direction of sample flow.
   e. Install a new capillary seal if you cannot remove the obstruction or the seal is excessively worn or damaged.

Figure 4-14. Removing Obstructions from the Capillary Seal

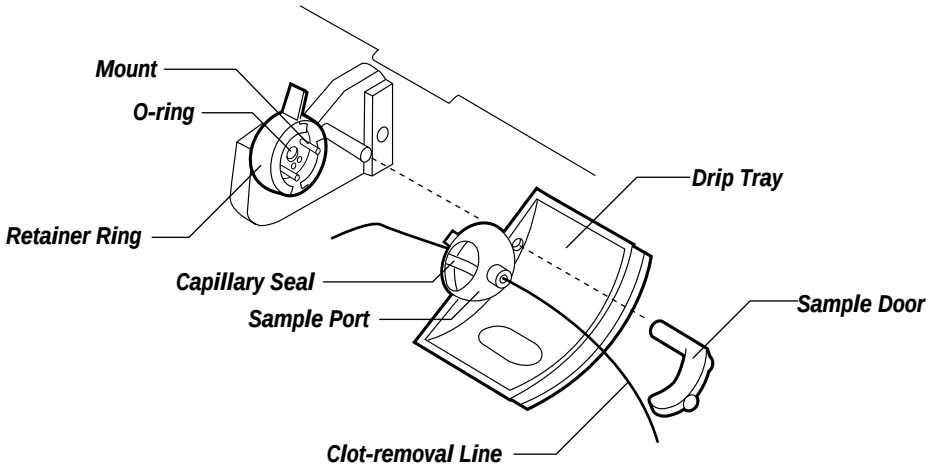


6. Remove obstructions from the sample port, as shown in Figure 4-15:
   a. Pull the sample door off.
   b. Grasp the tab on the retainer ring and rotate the ring toward you.
   c. Grasp the sample port and drip tray and pull it to the right to remove it.

   NOTE: The sample port and the drip tray are one piece.

   d. Push a 0.558 mm (0.022-inch) diameter clot-removal line through the sample port from left to right, opposite the direction of sample flow.

Figure 4-15. Removing Obstructions from the Sample Port



7. Inspect the mount for obstructions and clean if necessary.
8. After removing any obstructions, reinstall the sample port:

   NOTE: Ensure that the three O-rings are in place on the mount.

   a. Reinstall the sample port onto the mount, matching the tab on the sample port to the notch in the retainer ring.
   b. Grasp the tab on the retainer ring and turn the retainer ring away from you to lock it in place.
   c. Replace the sample door, and ensure that it snaps into place.
9. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
10. Press **Yes** to perform a two-point calibration.
11. Analyze QC material as necessary to verify sensor performance.

Removing Obstructions from the Measurement Module

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code 2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Open the measurement module door:
   a. Push up the door latches located on the lower corners of the module door and lift up the door.
   b. Push the spring-loaded latch to the right.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

3. Inspect the pO_2 and pCO_2 (gas) sensors for obstructions:

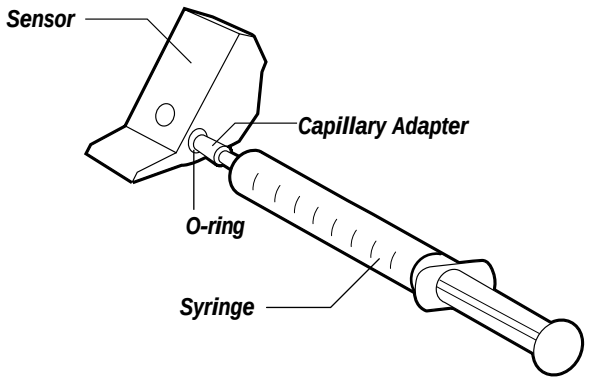
CAUTION: To avoid damage to the sensors, do not attempt to push the clot-removal line through the gas sensors.

   a. Remove the sensors and inspect the sample path for obstructions.
   b. Place a piece of tubing, or use a capillary adapter, on the tip of a syringe.

CAUTION: Do not exert excessive pressure on the gas sensor membrane.

   c. Place the syringe against the sensor sample path and inject air through the sensor as shown in Figure 4-16.

Figure 4-16. Using a Syringe to Clear a Sensor



NOTE: Use wash reagent that has not expired and has not been open longer than 60 days. Do not install the wash reagent bottle that you use for this procedure on the system.

d. If the obstruction is not removed, fill the syringe with fresh wash reagent and inject the wash reagent into the sensor sample path.

e. Dry thoroughly and reinstall the gas sensors, ensuring that the O-rings are in place.

⚠ **CAUTION:** To avoid damage to the sensors, use the clot-removal line carefully. Be particularly careful with the pH sensor.

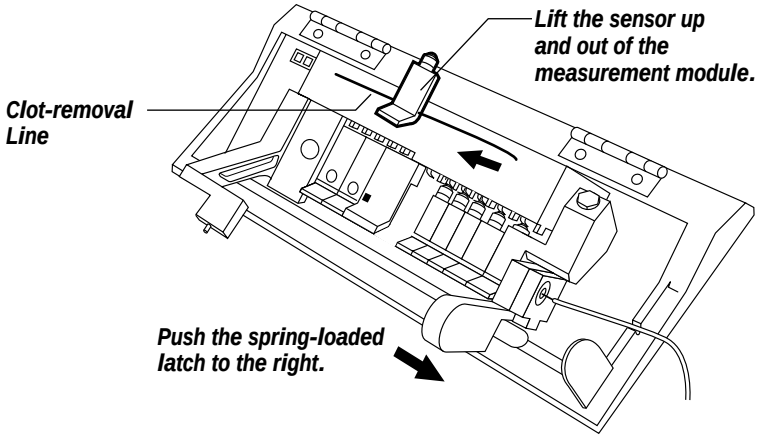
4. Inspect the reference sensor, the sample ground/temperature sensor, pH sensor, and the Na^+ sensor for obstructions:

   a. Remove the sensors one at a time and inspect the sample path for obstructions.

   b. Cut a piece of tubing, or use a capillary adapter, and place the tubing on the tip of the syringe.

   c. Push a 0.558 mm (0.022-inch) diameter clot-removal line through the sensor to remove obstructions, as shown in Figure 4-17.

Figure 4-17. Removing Obstructions from a pH, Na^+, Reference, or Sample Ground/Temperature Sensor on an 850



   d. If the obstruction is not removed, cut a piece of tubing, or use a capillary adapter, and place the tubing on the tip of the syringe.

   e. Place the syringe against the sensor sample path and inject air through the sensor to remove obstructions.

   f. If the obstruction is not removed, fill the syringe with fresh wash reagent and inject the wash reagent into the sensor sample path.

CAUTION: Touch the inner surface of the module frame to discharge static buildup before removing or returning sensors.

g. Dry thoroughly and reinstall each sensor, ensuring that the O-rings are in place.

CAUTION: To avoid damage to Ca^{++}, Cl^{-}, K^{+}, Glu, and Lac sensors, do not attempt to push the clot-removal line through these sensors.

5. Inspect the Ca^{++}, Cl^{-}, K^{+}, Glu, and Lac sensors for obstructions:

a. Remove the sensors one at and inspect each one for obstructions.

860 **CAUTION:** Do not exert excessive air pressure on the glucose or lactate sensor membrane.

b. Place the syringe against the sensor sample path and inject air through the sensor to remove obstructions.

c. If the obstruction is not removed, fill the syringe with fresh wash reagent and inject the wash reagent into the sensor sample path to remove obstructions.

860 **NOTE:** As you install the biosensors, ensure that the biosensors are in the correct location. Visually verify that you align the contacts on the biosensors with the contacts in the measurement module.

d. Dry thoroughly and reinstall each sensor, ensuring that the O-rings are in place.

6. Remove obstructions from the preheater:

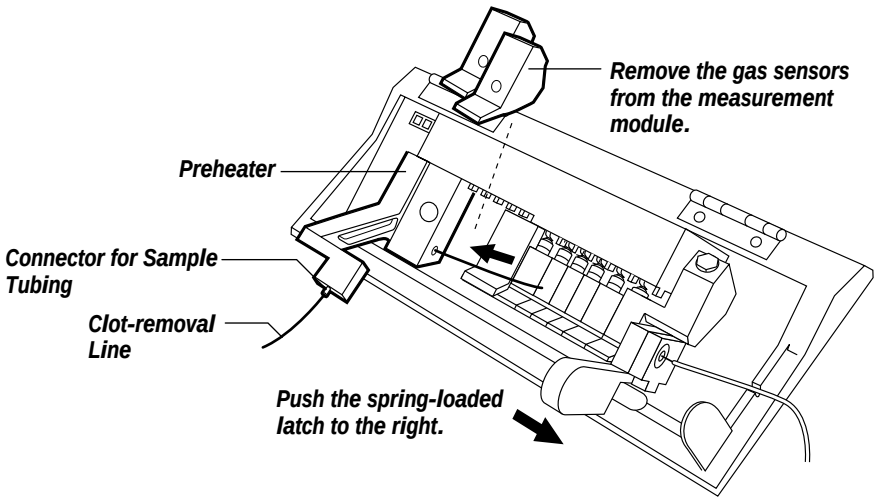
CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

a. Remove the gas sensors.

b. Disconnect the sample tubing from the preheater.

c. Push a clot-removal line through the preheater from right to left, opposite to the direction of sample flow, as shown in Figure 4-18.

Figure 4-18. Removing Obstructions from the Preheater on an 850



d. Connect the sample tubing to the preheater.

e. Reinstall the gas sensors, ensuring that the O-rings are in place.

7. Remove obstructions from the path through the latch, as shown in Figure 4-19:

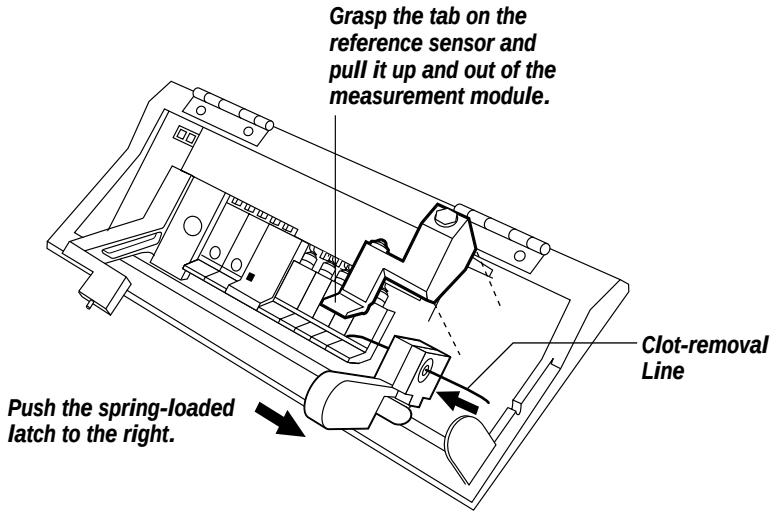
CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

a. Grasp the tab on the reference sensor and pull it up and out of the measurement module.

b. Remove the tubing from the spring-loaded latch.

c. Push a clot-removal line through the latch.

Figure 4-19. Removing Obstructions from the Spring-Loaded Latch on an 850



d. Connect the measurement module tubing to the latch.

e. Reinstall the reference sensor, ensuring that O-rings are in place.

8. Press the release tab to close the spring-loaded latch.
9. Ensure that the sensors are aligned correctly.
10. Close the measurement module door.
11. Press **Continue**.

    A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.
12. Allow the system to warm up at least 15 minutes.
13. Press **Yes** to perform a two-point calibration.
14. Analyze a minimum of two levels of QC material to verify sensor performance.

Removing Obstructions from the CO-ox Sample Path

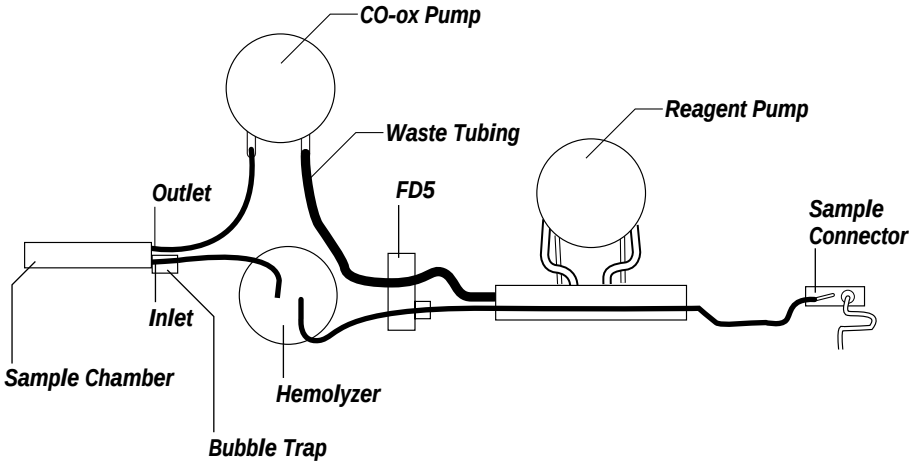
BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

NOTE: Do not use a needle on the syringe that you use to introduce reagent water or air into the CO-ox sample tubing. Using a needle may damage the CO-ox sample tubing.

Menu Code
2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Inspect the CO-ox sample tubing and waste tubing for obstructions, as shown in Figure 4-20.

Figure 4-20. CO-ox Sample and Waste Tubing



NOTE: Do not move the obstruction into the hemolyzer, sample chamber, or sample connector.

If the obstruction is . . .	***Then . . .***
in the CO-ox sample tubing that connects the hemolyzer and bubble trap or the sample chamber and CO-ox pump	a. Remove the piece of sample tubing that contains the obstruction. b. Push a clot-removal line, less than 0.020 mm diameter, through the tubing to remove the clot. c. Reinstall the sample tubing.
in the CO-ox sample tubing that connects the sample connector and the hemolyzer	a. Disconnect the end of the CO-ox sample tubing that is closest to the obstruction. b. If you disconnected the sample tubing from the sample connector, disconnect the waste tubing from the inlet on the reagent manifold and manually turn the CO-ox pump counterclockwise to remove the obstruction. **NOTE:** If air does not remove the obstruction, place the waste tubing into a beaker of reagent water, and manually turn the CO-ox pump counterclockwise to remove the obstruction. c. If you disconnected the sample tubing from the hemolyzer, disconnect the sample pump tubing on the base model from the right connector 4. Attach a piece of tubing to a two-way connector and attach the connector to the pump tubing. Manually turn the sample pump counterclockwise to remove the obstruction. **NOTE:** If air does not remove the obstruction, place the sample tubing into a beaker of reagent water and manually turn the sample pump counterclockwise to remove the obstruction. d. If the obstruction is not removed, replace the sample tubing.

3. Inspect the sample connector for obstructions:
   a. Disconnect the tubing from the sample connector.
   b. Remove the sample connector.
   c. Push a clot-removal line through the sample connector to remove obstructions.

   NOTE: If the obstruction is in the preheater, see *Removing Obstructions from the Measurement Module* for instructions.

   d. Reinstall the sample connector.
   e. Reconnect the tubing.
4. Inspect the hemolyzer for obstructions:
   a. Remove the anvil cap on the hemolyzer by turning it a quarter turn counterclockwise.
   b. Disconnect the sample tubing from the anvil.
   c. Pull the anvil and anvil spring away from the mounting pin on the hemolyzer.
   d. Push a clot-removal line through the tubing connectors on the anvil.
   e. Clean the exterior surface.
   f. Reassemble the hemolyzer.

5. Inspect the sample chamber and bubbletrap for obstructions:

If the obstruction is . . .	***Then . . .***
near the sample chamber outlet	a. Disconnect the CO-ox sample tubing from the sample connector. b. Manually turn the CO-ox pump clockwise. c. Move the obstruction just into the sample tubing that connects the sample chamber to the CO-ox pump. **NOTE:** If air does not remove the obstruction from the sample chamber, place the sample tubing from the sample connector into a beaker of reagent water. Turn the CO-ox pump clockwise to remove the obstruction. d. Disconnect the sample tubing from the sample chamber outlet. e. Disconnect the CO-ox waste tubing from the inlet on the reagent manifold. f. Manually turn the CO-ox pump counterclockwise to remove the obstruction from the sample tubing. **NOTE:** If air does not remove the obstruction from the sample tubing, place the CO-ox waste tubing in water. Turn the CO-ox pump counterclockwise to remove the obstruction. g. Reconnect all tubing.
near the sample chamber inlet	a. Disconnect the waste tubing from the inlet on the reagent manifold. b. Disconnect the sample tubing from the bubble trap and the sample chamber inlet. c. Manually turn the CO-ox pump counterclockwise to remove the obstruction. **NOTE:** If air does not remove the obstruction from the sample tubing, place the waste tubing into a beaker of reagent water. Turn the CO-ox pump counterclockwise to remove the obstruction. d. Reconnect all tubing.

(Continued)

If the obstruction is . . .	*Then . . .*
not removed	a. Remove the sample chamber. **NOTE:** Hold the sample chamber by the edges. b. Disconnect the bubble trap from the sample chamber. c. Push a clot-removal line through the two sample chamber ports. d. Clean the glass sapphire window. e. Reconnect the bubble trap to the sample chamber. f. Reinstall the sample chamber. g. Perform a one-point calibration. h. Perform a tHb slope calibration.
in the bubble trap	a. Disconnect the tubing from the bubble trap. b. Disconnect the bubble trap from the sample chamber. c. Push a 0.016-inch diameter clot-removal line into the metal tubing of the outlet port of the bubble trap. **NOTE:** If the clot-removal line does not remove the obstruction, flush the bubble trap by injecting reagent quality water into the metal port using a syringe and a separate piece of tubing or capillary adapter. d. Reconnect the bubble trap to the sample chamber. e. Reconnect the tubing to the bubble trap.

6. Press **Continue**.

   A wash sequence starts. When the wash sequence finishes, a message box appears prompting you to perform a two-point calibration.

7. Press **No**.

Menu Code
(from the Main Menu)
1 ***1***

8. Perform a one-point calibration from the Menu screen:
   a. Select **1 Calibration** and press **Enter**.
   b. Select **1 One-point** and press **Enter**.

Disconnecting the CO-ox Sample Path

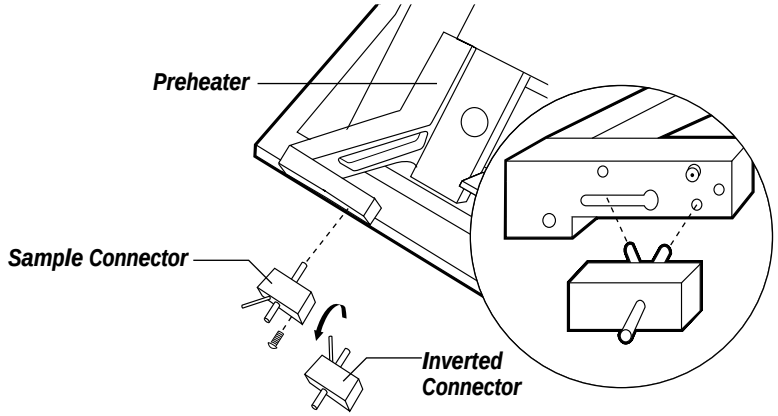
Use this procedure to disconnect the CO-ox sample path from the base model. You can continue to measure the remaining parameters.

BIOHAZARD: Refer to Appendix A, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Menu Code 6 3

1. Turn the CO-ox parameters off:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **3 Parameters** and press **Enter**.
   c. Move to the CO-oximetry frame.
   d. Select the tHb parameter and press **Enter**.
      This turns all CO-ox parameters off.
   e. Press **Next Screen** to access the second screen of parameters.
   f. Press **Next Screen** to access the third screen of parameters.
   g. Press **Done** when you finish.
2. Disconnect the CO-ox and base model sample tubing from the sample connector.
3. Remove the screw from the sample connector.
4. Invert the sample connector so that the "Y" is on the bottom as shown in Figure 4-21.

Figure 4-21. Disconnecting the CO-ox Sample Path



5. Align the sample connector with the guide pin and slide the “Y” prongs into the slot at the bottom of the face plate.

   The straight path is on top when the CO-ox sample path is disconnected.

6. Reinstall the screw.
7. Reconnect the base model sample tubing.
8. Press **OK**.

Procedural Notes

To reconnect the CO-ox sample path, turn the CO-ox parameters on, invert the sample connector. The instructions in the procedure for disconnecting the sample path describe how to invert the sample connector. When the connector is inverted and the “Y” is on top, reconnect the CO-ox and base model sample tubing. Press OK.

System Troubleshooting

This section describes information about observed problems that are not usually associated with diagnostic codes (D codes), that appear as system messages requiring operator intervention, or that are not cleared by a diagnostic test.

Use the appropriate subsections to troubleshoot the following:

- results
- reagents
- sensors and CO-ox
- bar codes
- electronics
- roll printer
- probe
- pumps
- thermal control
- system messages

If the problem remains after you perform the suggested solutions, contact your Service Representative.

Troubleshooting Results

Use this section to troubleshoot observed problems in the following:

- quality control results
- patient results

Troubleshooting Quality Control Results

Use this table if you observe quality control results that are outside the expected range or proficiency test results that are not as expected.

Problem	Probable Cause and Solutions
_ _ _ _ _ _↑ or _ _ _ _ _ _↓ or Out of Range message	The result is above (up arrows) or below (down arrows) the limits of the system's measurement range, as described in Appendix E, *Performance Characteristics*. 1. Verify the manufacturer's control values and ascertain whether a value outside the system's measurement range is likely. 2. Check for sample movement during measurement. 3. Check the fluid in the sample path for bubbles. 4. Perform a wash. 5. Retest the control if appropriate. 6. Check pH, ISE, and reference sensor fill levels. 7. Perform a successful two-point calibration. 8. Verify that the control is prepared, handled, and stored correctly. 9. Test a new set of controls. 10. Verify that the sample pump is operating correctly and test the sample pump flow rate as described in *Pump Functions Test*, page 4-58.
↑ or ↓ ↑↑ or ↓↓	The result is above (up arrow) or below (down arrow) the established control range. 1. Verify that the control is prepared, handled, mixed, and sampled correctly. 2. Review the control manufacturer's storage instructions. Avoid storing controls near heated or cooled areas, such as the system, a heating vent, or an air conditioner vent. 3. Verify that the controls are not outdated or deteriorated. Use controls only within their expiration date. 4. Verify that the reagents are not outdated. 5. Perform a successful two-point calibration. 6. Check for sample movement during measurement. 7. Check the fluid in the sample path for bubbles. 8. Perform a wash. 9. Retest the control. 10. Ensure that sensors are filled with the appropriate solutions and are free of bubbles. 11. Verify that the sample pump is operating correctly and test the sample pump flow rate as described in *Pump Functions Test*, page 4-58.

(Continued)

Problem	Probable Cause and Solutions
Proficiency test results are not as expected	System requires cleaning or maintenance, or reagents or controls are outdated, deteriorated, or incorrectly handled. 1. Perform all required maintenance and cleaning. 2. Ensure that reagents, controls, and unknown samples are prepared, handled, and stored correctly. 3. Check all quality control results. 4. Check any unusual occurrences such as error flags or irreproducible results. 5. Check reagent and instrument reporting categories for transcription or setup errors. 6. Verify that the controls are not outdated or deteriorated. Use controls only within their expiration date. 7. Verify that the reagents are not outdated. 8. Perform a successful two-point calibration. 9. Check for sample movement during measurement. 10. Check the fluid in the sample path for bubbles. 11. Perform a wash. 12. Ensure that sensors are filled with the appropriate solutions and are free of bubbles. 13. Verify that the sample pump is operating correctly and test the sample pump flow rate as described in *Pump Functions Test*, page 4-58.

Troubleshooting Patient Results

Use this table if you observe unexpected or out-of-range patient results.

Problem	Probable Cause and Solutions
The patient sample result is not as expected	The result is inconsistent with the patient's diagnosis, current treatment, or past history including previous measurements on that patient, or is inconsistent with other values on the same specimen. 1. Ensure that you use the correct sample collection techniques and anticoagulant, as described in *Sample Collection Devices and Anticoagulants* in Section 1. 2. Ensure that you use the recommended storage, handling, and mixing techniques. 3. Retest the sample. Ensure that the sample, especially those from capillary tubes, has no air bubbles. 4. Check for sample movement during measurement. 5. Ensure that reagents are installed in the correct positions on the manifold. 6. Perform a wash. 7. Perform a successful two-point calibration. 8. Retest the sample and verify the results.
* is printed next to the result on reports	A measurement sensor does not reach the endpoint within 90 seconds (glucose within 60 seconds). 1. Retest the sample. 2. Verify that cleaning and maintenance procedures have been performed. If not, deproteinize and condition the sensors. 3. Ensure that you use the correct sample collection techniques and anticoagulant, as described in *Sample Collection Devices and Anticoagulants* in Section 1. 4. Check for sample movement during measurement. 5. Check the fluid in the sample path for bubbles. 6. Ensure that you use the recommended storage, handling, and mixing techniques. 7. Check for salt deposits and leaks around the sensors. Clean and refill sensors, if required. 8. If the problem recurs repeatedly, replace the sensor.

(Continued)

Problem	Probable Cause and Solutions
_ _ _ _ _ _↑ or _ _ _ _ _ _↓ or Out of Range message	The result is above (up arrows) or below (down arrows) the limits of the system's measurement range, as described in Appendix E, *Performance Characteristics*. 1. Check the source and result, and ascertain whether a value outside the range is likely. 2. Check for sample movement during measurement. 3. Check the fluid in the sample path for bubbles. 4. Perform a wash. 5. Ensure that you use the correct sample collection techniques and anticoagulant, as described in *Sample Collection Devices and Anticoagulants* in Section 1. 6. Ensure that you use the recommended storage, handling, and mixing techniques. 7. Retest the sample.
↑ or ↓ ↑↑ or ↓↓	The result is above (up arrow) or below (down arrow) the established range. 1. Check the sample source and result, and ascertain whether a value outside the range is likely. 2. Check for sample movement during measurement. 3. Check the fluid in the sample path for bubbles. 4. Perform a wash. 5. Ensure that you use the correct sample collection techniques and anticoagulant, as described in *Sample Collection Devices and Anticoagulants* in Section 1. 6. Ensure that you use the recommended storage, handling, and mixing techniques. 7. Retest the sample.
# is printed next to the glucose or lactate result on reports	The system detects substances in the sample that may interfere with glucose or lactate measurement. 1. Check the sample source and determine whether the presence of an interfering substance is likely. See Appendix E, *Performance Characteristics*, for a list of interfering substances. 2. If the message appears on multiple patient samples that do not contain interfering substances, replace the appropriate biosensor, as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.

(Continued)

Problem	Probable Cause and Solutions
? is printed next to the CO-oximeter results on reports	Optical measurements indicate that the CO-oximeter results should be reviewed. Results may still be clinically valid. When reporting CO-oximeter results, consider the patient's history and clinical condition to determine acceptability of results. To troubleshoot an *If Blood, Question Data* message, determine whether the problem is with the sample type, the patient sample, or the system. **NOTE:** When analyzed as a patient sample, aqueous materials with dyes cause the *If Blood, Question Data* message to appear. 1. Ensure that you analyzed a patient sample, not a QC or calibration sample. Ensure that the patient sample is free of clots and unidentified interfering substances. 2. If the problem is not with the sample type, analyze the sample again. 3. If the message reappears, perform a pH/lytes one-point calibration to zero the CO-oximeter.

If the calibration . . .	Then . .
is successful	go to step 5.
is not successful	repeat the pH/lytes one-point calibration two more times.

(Continued)

Problem	Probable Cause and Solutions
? is printed next to the CO-oximeter results on reports	4. Review the last calibration.

If the calibration . . .	Then . . .
is successful	go to step 5.
is not successful	a. Clean the sample chamber. Refer to *Cleaning the Sample Chamber* in Section 3. b. Check that the hemolyzer is correctly assembled and that the gasket is in place. c. Perform a pH/lytes one-point calibration and then perform a tHb slope calibration. d. Analyze the sample again. e. If the message reappears, go to step 6.

5. Obtain and analyze a new sample from the patient.
6. If the message reappears, the problem may be with the patient. Analyze a sample from a different patient.
7. If the message reappears, contact your Service Representative.

Troubleshooting Reagent Problems

This section contains information to troubleshoot observed problems with the following:

- fluid leaks
- insufficient fluid flow
- cloudiness or particulate matter
- gas leaks

Fluid Leaks

Use this table if you observe fluid leaks in or under the 800 system.

Problem	Probable Cause and Solutions
Sample drips out of sample port	1. Ensure that you do not inject the sample into the sample port. 2. Ensure that the syringe is fully seated in the sample port before you press Analyze. 3. Ensure that all parts of the sample port, including the capillary seal, retainer ring, and O-rings are installed correctly and are not deteriorated. 4. Check the sample pump tubing for worn areas or leaks at fittings. Replace worn or leaking tubing as described in *Replacing the Pump Tubing* in Section 3. 5. Test the sample pump flow rate as described in *Pump Functions Test,* page 4-58.
Fluid is leaking from the left side of the sample port	1. Ensure that the sample probe is installed correctly. 2. Check that the O-rings are installed on the sample port and are not deteriorated.
Fluid is leaking in the measurement module	1. Verify that all sensor O-rings are aligned with the sample path and that they are not deteriorated. Verify that the sensors are installed correctly. **NOTE:** The reference sensor has two O-rings. 2. Check that sample tubing and measurement module tubing are installed correctly.
Reagent is leaking from the reagent module, bottle, or fitting	1. Ensure that bottles are installed correctly and fit securely on the reagent fittings. 2. Check the O-rings on the back of the reagent fittings. 3. Install a new bottle of Bayer Diagnostics reagent. 4. Check the valve function as described in *Valves Test,* page 4-62.
Fluid is leaking from the tubing	1. Check the tubing connections. 2. Replace the tubing if it is deteriorated.

Insufficient Fluid Flow

Use this table if you observe problems with fluids flowing too slowly, erratically, or not at all.

Problem	Probable Cause and Solutions
Insufficient wash solution is flowing to clean the sample path	1. Check the level of wash reagent and install a new bottle of Bayer Diagnostics wash reagent if required. 2. Ensure that the bottle of wash reagent is seated correctly on the reagent manifold. 3. Check the reagent fitting for obstructions. 4. Install a new bottle of Bayer Diagnostics wash reagent. 5. Inspect the sample path in the measurement module for obstructions and leaks. 6. Verify that all sensor O-rings and sensors are correctly aligned with the sample path and that the O-rings are not deteriorated. **NOTE:** The reference sensor has two O-rings. 7. Inspect all tubing and fittings for leaks. 8. Check the waste outlets for obstructions. 9. Verify that the wash, foam, and diverter valves are operating correctly as described in *Valves Test*, page 4-62. 10. Test the reagent pump flow rate as described in *Pump Functions Test*, page 4-58, and verify that the pump is operating correctly. 11. Clean the roller cage and shaft and replace the pump tubing if required.

(Continued)

Problem	Probable Cause and Solutions
Insufficient wash solution is flowing through the sample port	1. Check the level of wash reagent and install a new bottle of Bayer Diagnostics wash reagent if required. 2. Ensure that the bottle of wash reagent is seated correctly on the reagent manifold. 3. Check the wash reagent fitting for obstructions. 4. Check the sample port for obstructions or leaks and ensure that it is installed correctly. 5. Inspect the capillary seal and O-rings for proper installation and for deterioration. Reinstall or replace them if required. 6. Check the sample tubing for obstructions or leaks. 7. Check the sample pump tubing for worn areas or leaks at the fittings. 8. Test the reagent pump flow rate as described in *Pump Functions Test*, page 4-58, and verify that the pump is operating correctly. 9. Clean the roller cage and shaft and replace the pump tubing if required.
No waste is flowing out of the waste outlets into the waste bottle	1. Check for obstructions in the sample entry components as described in *Removing Obstructions from the Sample Entry Components*, page 4-79. 2. Check for obstructions in the measurement module as described in *Removing Obstructions from the Measurement Module*, page 4-82. 3. Check for obstructions in the CO-ox module as described in *Removing Obstructions from the CO-ox Sample Path*, page 4-87. 4. Check for obstructions in the measurement tubing and waste outlets. 5. Ensure that the sample port, retainer ring, and O-rings are installed correctly and not leaking. 6. Inspect the sample pump and waste pump tubing for obstructions and leaks, and inspect the roller cages and shafts. 7. Test the sample pump and waste pump flow rates as described in *Pump Functions Test*, page 4-58, and verify that the pumps are operating correctly.

(Continued)

Problem	Probable Cause and Solutions
Sample path is obstructed	The fluid flow is insufficient due to obstructions in the sample path. 1. Check for obstructions in the sample entry components as described in *Removing Obstructions from the Sample Entry Components*, page 4-79. 2. Check for obstructions in the measurement module as described in *Removing Obstructions from the Measurement Module*, page 4-82. 3. Check for obstructions in the measurement module tubing and waste outlets. 4. Check for obstructions in the CO-ox module as described in *Removing Obstructions from the CO-ox Sample Path*, page 4-87. 5. Inspect all connections and fittings for obstructions and leaks. 6. Verify that all sensor O-rings and sensors are correctly aligned with the sample path and that the O-rings are not deteriorated. **NOTE:** The reference sensor has two O-rings. 7. Test the sample pump flow rate as described in *Pump Functions Test*, page 4-58, and verify that the pump is operating correctly.
Air bubbles in fluid in sample path	1. Check your sampling technique as described in *Sample Collection Devices and Anticoagulants* in Section 1. 2. Verify that all sensor O-rings and sensors are correctly aligned with the sample path and that the O-rings are not deteriorated. **NOTE:** The reference sensor has two O-rings. 3. Check the sample probe and the sample tubing for damage or incorrect installation. 4. Test the reagent and sample pump flow rates as described in *Pump Functions Test*, page 4-58, and verify that the pumps are operating correctly.

(Continued)

Problem	Probable Cause and Solutions
During the first 24 hours following installation, the glucose or lactate biosensors measure a large negative slope value during calibration. The biosensors measure an equal, but positive slope valve during the next calibration.	The shift in slope value is due to bubbles trapped in the glucose or lactate biosensor. Analyze several blood samples sequentially. **NOTE:** The problem may clear itself if no blood samples are analyzed for 12 – 24 hours.
Erratic sample flow	The fluid flow is insufficient due to clots in the sample or to obstructions in the sample path. 1. Check your sampling technique as described in *Sample Collection Devices and Anticoagulants* in Section 1. 2. Check for obstructions in the sample entry components as described in *Removing Obstructions from the Sample Entry Components*, page 4-79. 3. Check for obstructions in the measurement module as described in *Removing Obstructions from the Measurement Module*, page 4-82. 4. Check for obstructions in the CO-ox module as described in *Removing Obstructions from the CO-ox Sample Path*, page 4-87. 5. Verify that all sensor O-rings and sensors are correctly aligned with the sample path and that the O-rings are not deteriorated. **NOTE:** The reference sensor has two O-rings. 6. Verify that the hemolyzer gasket on the CO-ox module is seated correctly. 7. Verify that the sample chamber gasket on the CO-ox module is seated correctly. 8. Test the sample pump flow rate as described in *Pump Functions Test*, page 4-58, and verify that the pump is operating correctly.

Cloudiness or Particulate Matter

Use this table if you observe fluids with cloudiness, color changes, or particulate matter.

Problem	Probable Cause and Solutions
A reagent is cloudy or has particulate matter	The reagent may be outdated or deteriorated. 1. Remove the reagent, and then prime the lines to purge all reagent from the system. 2. Install a new bottle of Bayer Diagnostics reagent. 3. Prime the system with the reagent. 4. Check the fill solution level in the sensors, and empty and refill if required. 5. Initiate the Auto Clean sequence. 6. Perform two successful two-point calibrations. 7. Run controls and verify the results.
The sample path is cloudy or has particulate matter	The sample path may require cleaning or routine maintenance. 1. Deproteinize the sample path and condition the sensors as described in Section 3. 2. Inspect reagents and replace any reagents that are outdated or deteriorated. 3. Prime the system with the reagent. 4. Perform a successful two-point calibration.

Gas Leaks

Use this table if you observe problems with the supply and delivery of Cal or Slope Gas.

Problem	Probable Cause and Solutions
Leaking or hissing of gas	1. Locate the source of the leak by listening closely for hissing around the regulators and gas tubing. Apply soapy water around the regulator or the gas fittings on the reagent manifold and look for bubbles. **NOTE:** Do not apply any fluids to the area behind the reagent manifold. 2. Ensure that the connections are tight. 3. If you find a leak in the tubing, replace the tubing as described in *Replacing the Gas Tubing* in Section 3. 4. Check the regulators for leaks and replace if required. 5. Ensure the seal is in place between the gas tank and regulator. 6. If the leak is between the gas tank and regulator, tighten the yoke screw or replace the plastic seal. 7. Test the gas flow rate as described in *Checking the Gas Flow*, page 4-64.

Troubleshooting the Sensors

Use this table if you observe problems with any of the sensors. Also refer to *Removing Obstructions from the Measurement Module*, page 4-82.

Problem	Probable Cause and Solutions
More than one sensor shows excessive drift	1. If the pH or ISE sensors show drift, check the reference sensor for salt deposits and leaks. 2. If the gas sensors show drift, check the gas supplies.
Sensors with drift also show reagent problems	1. Correct the reagent problems in this order: D23, D24, and D29. 2. Correct the drift problem (D2, D3, D4, or D5).

(Continued)

Problem	Probable Cause and Solutions
Salt deposits appear in measurement module	1. Check the reference sensor for leaks. Tighten cap if required and clean any deposits with a swab moistened in reagent water. 2. Clean deposits in measurement module and on all sensors with swabs moistened in reagent water. 3. Verify that all sensor O-rings and sensors are correctly aligned with the sample path and that the O-rings are not deteriorated. **NOTE:** The reference sensor has two O-rings.
Fluid in sensor too low	Refill the sensor. Refer to the appropriate procedure in Section 3.
More than two sensors have a D4 Offset Error	1. If the pH or ISE sensors show offset errors, check the reference sensor for the correct solution level, salt in the vent hole, bubbles in the sensor, or leaks. 2. If the gas sensors show offset errors, check the gas supplies. 3. For a K^+ or Ca^{++} sensor, replace the fill solution even if it is sufficient.
Sensor fails the measurement test	An open circuit sensor contact or an electronic failure has occurred, or a fluid leaked into the preamplifier assembly. 1. Ensure that the sensor is installed correctly. 2. Wipe the contact on the sensor with a clean lint-free tissue. 3. Replace the sensor.

Troubleshooting Bar Codes

Use this table if you observe problems with bar codes or the bar code scanner.

Problem	Probable Cause and Solution
The bar code scanner works intermittently	Faulty scanning technique, poor bar code print quality, or loose cable connection to the port on the 800 system. 1. Check the bar code scanner, cable, and cable connections. 2. Check system setup to ensure that the bar code scanner is enabled. 3. Ensure that you are scanning the correct bar code symbol for the sample or control. 4. Test the bar code scanner as described in *Bar Code Scanner Test*, page 4-77.
The system does not emit a beep and data does not appear on screen when you scan with the bar code scanner	Incorrect symbology selected in system setup; incorrect or defaced bar code labels; or faulty bar code scanner, cable, or port, incorrect field in focus. 1. Check system setup to ensure that the bar code scanner is enabled. 2. Ensure that you are scanning the correct bar code symbol for the sample or control. 3. Check the bar code scanner, cable, and cable connections. 4. Ensure that the labels were created with the correct symbology. 5. Ensure you have the correct field highlighted. 6. Ensure that the system has power. 7. Test the bar code scanner as described in *Bar Code Scanner Test*, page 4-77.

Refer to the *800 Series Bar Coding Features* technical bulletin for detailed information about the set up for the bar code features.

Troubleshooting Electronics

Use this table if you observe electronic problems.

Problem	Probable Cause and Solutions
The system does not respond to input from the keypad	1. If your system has a keyboard, check the keyboard to see if it is working, and ensure that Num Lock is turned off. 2. Disconnect the power cord from the power source. 3. Wait at least 10 seconds, and then connect the power cord to the power source.
An external device, LIS, or HIS does not respond to the system	1. Ensure the port is enabled as described in *Configuring for External Devices* in Section 5 and Appendix D, *Interfacing to External Devices*. 2. Check the cable connections at both ends. 3. Check the cable for crimps or deterioration. 4. Connect the external device, LIS, or HIS to another port as described in *Configuring for External Devices* in Section 5 and *Interfacing to External Devices* in Appendix D. 5. Perform the external loopback test as described in *External Loopback Test*, page 4-75. 6. Check the operation of the external device, LIS, or HIS.
No system power or screen is blank	1. Ensure the screen is adjusted to the correct viewing angle and brightness. 2. Ensure the power cord of the 800 system is connected to the electrical outlet. 3. Ensure the electrical outlet has power. 4. Check the system fuse.

Troubleshooting the Roll Printer

Use this table if you observe problems with the roll printer.

Problem	Probable Cause and Solutions
Printer is not printing at all	1. Ensure the thermal paper is feeding correctly and that it is not reversed. Refer to *Replacing the Printer Paper* in Section 3. 2. Check for a paper jam and clear it. 3. Remove paper dust if it has accumulated in the printer. 4. Ensure the system has power. 5. Check the operating setup to ensure that the roll printer report option is on.
Printer is not printing correctly	1. Test the roll printer as described in *Roll Printer Test*, page 4-76. 2. Clean the roll printer as described in *Cleaning the Roll Printer* in Section 3. 3. Repeat the Roll Printer Test. 4. Replace the roll of printer paper as described in *Replacing the Printer Paper* in Section 3 using Bayer Diagnostics paper.

Troubleshooting the Probe

Use this table if you observe problems with the sample probe. Refer to *Removing Obstructions from the Sample Entry Components*, page 4-79.

Problem	Probable Cause and Solutions
Sample probe is not working correctly	1. Ensure the sample probe is installed correctly and that it is clean. 2. Ensure the capillary seal is installed correctly. 3. Check the probe, sample port, probe mount, and capillary seal for obstructions. 4. Test the sample entry components as described in *Sample Entry Test*, page 4-67. 5. If the probe is damaged, replace the probe.

Troubleshooting the Pumps

Use this table if you observe problems with the reagent pump, sample pump, or waste pump.

Problem	Probable Cause and Solutions
Pump is not operating correctly	1. Inspect the pump tubing and replace if required. 2. Clean the roller cage and shaft as described in *Cleaning the Roller Cages* in Section 3. 3. Test the pump electronics and flow rate for the appropriate pump as described in *Pump Functions Test*, page 4-58.

Troubleshooting Thermal Control

Use this table if you observe problems with temperature control.

Problem	Probable Cause and Solutions
Measurement module temperature warning message	The measurement module is outside the 37.00 ± 0.15°C range. The system can accept sample analysis. 1. Ensure that the measurement module door is closed. 2. Perform the *Temperature/pAtm Test*, as described in Section 4, to check the sample temperature. 3. Wait at least 15 minutes for the system to warm up. 4. Verify that the location of the system meets the specifications for ambient operating temperatures, as described in Appendix H, *Installation*. 5. Check the air filter to ensure that the air vent is not obstructed and that the filter is clean. See *Replacing the Air Filter* in Section 3. 6. Verify that the fan is operating.

(Continued)

Problem	Probable Cause and Solutions
Measurement module temperature error message	The measurement module temperature is outside the 37.0 ± 0.5°C range. The system cannot accept sample analysis requests. 1. Ensure the measurement module door is closed. 2. Wait at least 15 minutes for the system to warm up. 3. Perform the *Temperature/pAtm Test*, as described in Section 4. 4. If the temperature control is off, press **Reset Control**. 5. Verify that the sample ground/temperature sensor is installed correctly. 6. Verify that the location of the system meets the specifications for ambient operating temperatures, as described in Appendix H, *Installation*. 7. Check the air filter to ensure that the air vent is not obstructed and that the filter is clean. See *Replacing the Air Filter* in Section 3. 8. Verify that the fan is operating.
CO-ox sample chamber temperature error message	The CO-ox sample chamber is outside the 37.00 ± 0.35°C range. The system cannot accept tHb sample measurement requests. 1. Perform the *Temperature/pAtm Test*, as described in Section 4. 2. If the temperature control is off, press **Reset Control**. 3. Wait at least 15 minutes for the system to warm up.

Troubleshooting System Messages

Use this table to troubleshoot system messages that appear during analysis mode functions. The system messages are listed in the status area of the Analysis Mode home screen.

Problem	Probable Cause and Solutions
Bubbles Detected in Sample	The system detects a non-continuous fluid in the measurement module sample path. The system asks whether you want to continue. 1. If the sample is not at point A or beyond, you can position the sample manually to continue with analysis. Press **Sample in Place**. 2. Ensure that you use proper sampling technique, as described in *Analyzing . . . Samples* in Section 2. **NOTE:** The reference sensor has two O-rings. 3. Verify that the sensor O-rings are not deteriorated and that all sensors and sensor O-rings are aligned correctly with the sample path. 4. Check the sample probe and the sample tubing for damage or incorrect installation. 5. Verify that the reagent and sample pumps are operating correctly and test the reagent and sample pump flow rates, as described in *Pump Functions Test* in Section 4.
COox Sample Chamber Temp Error	The CO-ox sample chamber is outside the 37.00 ± 0.35°C range. The system cannot accept tHb sample measurement requests. 1. Perform the *Temperature/pAtm Test*, as described in Section 4. 2. If the temperature control is off, press **Reset Control**. 3. Wait at least 15 minutes for the system to warm up.
COox Sample Temp Out of Range	The CO-ox sample chamber temperature is not in range at the end of the measurement sample. 1. Perform the *Temperature/pAtm Test*, as described in Section 4. 2. If the temperature control is off, press **Reset Control**. 3. Wait at least 15 minutes for the system to warm up.

(Continued)

Problem	Probable Cause and Solutions
Excessive Bubbles in COox Sample Excessive Bubbles in COox tHb Slope Excessive Bubbles in Zero	The system detects a non-continuous fluid in the CO-ox sample path. 1. Ensure that you use proper sampling technique, as described in *Analyzing . . . Samples* in Section 2. Analyze the sample again or perform a pH/lytes one-point calibration. 2. Check the CO-ox sample tubing for leaks, cracks, crimps, or loose connections, particularly at the inlet and outlet to the sample chamber. See *Replacing the CO-ox Sample Tubing* in Section 3. 3. Check the bubble trap for large bubbles. Clean or replace the bubble trap. 4. Check for obstructions in the CO-ox sample path. See *Removing Obstructions from the CO-ox Sample Path* in Section 4. 5. Check for clots in the hemolyzer. See *Cleaning the Hemolyzer* in Section 3. 6. Clean the sample chamber, as described in *Cleaning the Sample Chamber* in Section 3.
Excessive Scatter in COox Meas	Excessive scatter may be due to excessive lipids, unlysed cells or particles, or an abnormally high tHb level in the CO-ox sample. This message also appears if the hemolyzer is disconnected. 1. Check that the hemolyzer is assembled properly. 2. Clean the hemolyzer, as described in *Cleaning the Hemolyzer* in Section 3. 3. Check the sample source. Do not use syringes with carboxymethylcellulose. See *Sample Collection Devices and Anticoagulants* in Section 1. 4. Analyze a QC sample, which should not cause an excessive scatter message. 5. Clean the bubble and sample chamber, as described in *Cleaning the Sample Chamber* in Section 3.

(Continued)

Problem	Probable Cause and Solutions
If Blood, Question Data	Optical measurements indicate that the CO-ox results should be reviewed. A question mark (?) is printed next to the CO-ox results on reports. Results may still be clinically valid. When reporting CO-ox results, consider the patient's history and clinical condition to determine acceptability of results. To troubleshoot an *If Blood, Question Data* message, determine whether the problem is with the sample type, the patient sample, or the system. **NOTE:** When analyzed as a patient sample, aqueous materials with dyes cause the *If Blood, Question Data* message to appear. 1. Ensure that you analyzed a patient sample, not a QC or calibration sample. Ensure that the patient sample is free of clots and unidentified interfering substances. 2. If the problem is not with the sample type, analyze the sample again. 3. If the message reappears, perform a pH/lytes one-point calibration to zero the CO-oximeter

If the calibration . . .	Then . .
is successful	go to step 5.
is not successful	repeat the pH/lytes one-point calibration two two more times.

(Continued)

<table>
<tr><th>Problem</th><th>Probable Cause and Solutions</th></tr>
<tr><td>If Blood, Question Data</td><td>4. Review the last calibration.
<table>
<tr><th>If the calibration . . .</th><th>Then . .</th></tr>
<tr><td>is successful</td><td>go to step 5.</td></tr>
<tr><td>is not successful</td><td>a. Clean the sample chamber. Refer to Cleaning the Sample Chamber in Section 3.
b. Check that the hemolyzer is correctly assembled and that the gasket is in place.
c. Perform a pH/lytes one-point calibration and then perform a tHb slope calibration.
d. Analyze the sample again.
e. If the message reappears, go to step 6.</td></tr>
</table>
5. Obtain and analyze a new sample from the patient.
6. If the message reappears, the problem may be the result of the patient’s clinical condition. Analyze a sample from a different patient.
7. If the message reappears, contact your Service Representative.</td></tr>
<tr><td>Insufficient COox Sample</td><td>The CO-ox sample chamber does not detect the sample during the predefined time limit. The CO-ox measurement cannot be completed.
1. Ensure that the sample volume is sufficient for the sampling device used and the tests requested.
2. Ensure that the sample is red, i.e., a blood sample or a colored aqueous solution.
3. Check the CO-ox sample path for leaks, cracks, or loose connections. See Replacing the CO-ox Sample Tubing in Section 3.
4. Check the CO-ox sample path for obstructions. Remove obstructions, as described in Removing Obstructions from the CO-ox Sample Path in Section 4.
5. Verify that the CO-ox pump is operating correctly and test the flow rate of the CO-ox pump, as described in the Pump Functions Test in Section 4.</td></tr>
</table>

(Continued)

Problem	Probable Cause and Solutions
Insufficient Sample	There is not enough sample to fill the measurement block. You can manually position the sample for measurement. See *Analyzing Microsamples*, Steps 5-11, in Section 2. 1. Ensure that the sample volume is sufficient for the sampling device used and the tests requested. 2. Check sample entry components for leaks or obstructions. See *Removing Obstructions from Sample Entry Components* in Section 4. 3. Replace the sample tubing. 4. Verify that the sample pump is operating correctly and test the flow rate of sample pump, as described in the *Pump Functions Test* in Section 4.
Interfering Substance: Glu Interfering Substance: Lac	The system detects substances in the sample that may interfere with glucose or lactate measurement. # is printed next to the glucose or lactate result on reports. 1. Check the sample source and determine whether the presence of an interfering substance is likely. See Appendix E, *Performance Characteristics*, for a list of interfering substances. 2. If the message appears on multiple patient samples that do not contain interfering substances, replace the appropriate biosensor, as described in *Replacing the Glucose and Lactate Biosensors* in Section 3.
Interfering Substance: tHb	The CO-ox module detects substances in the sample that may interfere with CO-ox measurement. The system tries to correct the measurement to account for the substance. 1. Check the sample source and determine whether the presence of an interfering substance is likely. See Appendix E, *Performance Characteristics*, for a list of interfering substances. 2. If the message appears on multiple patient samples that do not contain interfering substances, clean the bubble trap and sample chamber, as described in *Cleaning the Sample Chamber* in Section 3.

(Continued)

Problem	Probable Cause and Solutions
Meas Module Temperature Error	The measurement module temperature is outside the 37.0 ± 0.5°C range. The system cannot accept sample analysis requests. 1. Ensure that the measurement module door is closed. 2. Wait at least 15 minutes for the system to warm up. 3. Perform the *Temperature/pAtm Test*, as described in Section 4. 4. If the temperature control is off, press **Reset Control**. 5. Verify that the sample ground/temperature sensor is installed correctly. 6. Verify that the location of the system meets the specifications for ambient operating temperatures, as described in Appendix H, *Installation*. 7. Check the air filter to ensure that the air vent is not obstructed and that the filter is clean. See *Replacing the Air Filter* in Section 3. 8. Verify that the fan is operating.
Meas Module Temperature Warning	The measurement module temperature is outside the 37.00 ± 0.15°C range. The system can accept sample analysis requests. 1. Ensure that the measurement module door is closed. 2. Perform the *Temperature/pAtm Test*, as described in Section 4, to check the sample temperature. 3. Wait at least 15 minutes for the system to warm up. 4. Verify that the location of the system meets the specifications for ambient operating temperatures, as described in Appendix H, *Installation*. 5. Check the air filter to ensure that the air vent is not obstructed and that the filter is clean. See *Replacing the Air Filter* in Section 3. 6. Verify that the fan is operating.

(Continued)

Problem	Probable Cause and Solutions
No Sample Device Detected	No sample device is detected in the sample port after you press Analyze and the sample door closes. 1. Ensure that you use proper sampling technique, as described in *Analyzing . . . Samples* in Section 2. 2. Perform the *Sample Entry Test*, as described in Section 4. 3. Analyze the sample again. 4. If the message appears repeatedly with capillary samples, replace the capillary seal.
Sample Temperature Out of Range	The measurement module block temperature is not in range at the end of the measurement sequence. 1. Verify that the sample ground/temperature sensor is installed correctly. 2. Perform the *Temperature/pAtm Test*, as described in Section 4, to check the temperature of the preheater. 3. Remove any obstructions in the preheater, as described in *Removing Obstructions from the Measurement Module* in Section 4.

5 System Administration

Page

Setting Up the System

This section describes the procedures for defining or changing 800 system setup parameters. Table 5-1 describes many of the tasks that you can do in setup and lists the setup menu option you select to perform each task.

Table 5-1. Setup Options

If you want to . . .	*Then select . . .*
create and edit QC files	Operating Setup and QC Setup
define the number of patient samples stored on the system	System Setup and System Options
select Auto ID and Auto Accept for QC samples	Operating Setup and QC Setup
define reference and action ranges	Operating Setup and Patient Data
define the Patient Information screen	Operating Setup and Patient Data
select fields to appear on the screen and in the printed reports	Operating Setup and Report Formats
select units of measure for parameter results	Operating Setup and Units/Defaults
select names for parameters	Operating Setup and Parameter Names
define drift limits	Operating Setup and Calibration Setup
select the calibration frequency	Operating Setup and Calibration Setup
define the calibration gas values	Operating Setup and Calibration Setup
select printing options	Operating Setup and Printing Options
define correlation coefficients	Operating Setup and Correlation
change the date and time	System Setup and Date and Time
select the parameters to be analyzed	System Setup and Parameters
select the panel the system uses to analyze samples	System Setup and Panels

(Continued)

If you want to . . .	*Then select . . .*
control various system functions such as beeper volume, auto move capillaries, auto send results, and reporting resolution	System Setup and Systems Options
select maintenance functions such as record, view, or schedule maintenance tasks	System Setup and Systems Options
configure the 800 systems for a 270, a printer, a bar code scanner, an LIS, or a data management system	System Setup and Communications
define passwords to protect operations and menu access	System Setup and Security Setup
select the language used on the screen and in the printed reports	Service and System Information
view system serial number, ID, install date, software version, and phone number for technical assistance	Service and System Information

Using Keys in Setup

You use the following keys while performing setup:

Press . . .	*To . . .*
Menu	access the Menu screen.
Clear Entry	delete either a single character or the entire contents of the current field. Press the key once to delete a single character. Press the key twice in rapid succession to delete the contents of the field.
Done	accept any selections or entries made in a screen and display the next or previous screen in the sequence.
Next Screen	display another screen that contains additional text fields and options for the setup function you are performing. This key appears only when another screen of information is available.

(Continued)

Press . . .	To . . .
Previous Screen	return to the frame or screen from which you entered the present screen. If you press this key after you make changes to the current screen, a message appears prompting you to save your changes. Press Yes to save changes. Press No if you do not want to save your changes. If you made no changes, the prompt does not appear.
Reset Default Values	reset the values for a system parameter to the values entered by Bayer Diagnostics during manufacture. When you press this key, a message appears prompting you to reset the Bayer Diagnostics values. Press Yes to reset the values.
Exit Menu	return the system to the Ready screen.
Cancel	discontinue the setup procedure.
Enter	accept data you type in fields and selections you make on screens. Enter also lets you move forward through fields. Enter is located on the keypad.
Home	return you to the Ready screen. If you made changes to a screen, a message appears prompting you to save your changes. Press Yes to save changes. Press No if you do not want to save your changes. If you made no changes, the prompt does not appear. Home is located on the keypad.

Viewing System Information

Use this procedure to view system information:

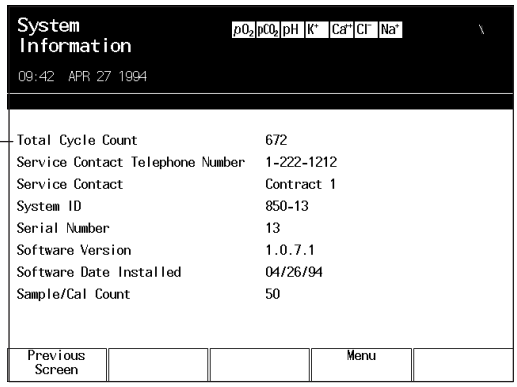
- service contact telephone number
- service contact
- system ID
- serial number
- CO-ox module serial number
- software version
- date software installed
- total cycle count (number of patient samples, QC samples, calibrations, and operator initiated washes)
- sample and calibration count (total of all patient samples and calibrations)

Menu Code
8 1

1. Access the System Information screen from the Menu screen:
   a. Press **8 Service Setup** and press **Enter**.
   b. Press **1 System Information** and press **Enter**.
   The System Information screen appears, as shown in Figure 5-1.

Figure 5-1. System Information Screen for an 850

Total cycle count is the number of patient samples, QC samples, calibrations, and operator-initiated washes.



2. Press **Menu** when you finish viewing the screen.
3. Define another setup function or press **Exit Menu** to return to the Ready screen.

Defining the Patient Information Screen

Use this procedure to select the fields you want to use in the Patient Information screen. The Patient Information screen can contain 16 fields. The default for each field is On, which means that all fields appear on the Patient Information screen. You can choose to have a field not appear on the form by turning the field off.

Certain fields can be made required fields. Required fields are fields that must be completed to continue with analysis. You can make a field required by selecting the check box next to the field. The default for required fields is Off, which means that none of the fields are required. Table 5-2 describes the Patient Information fields.

Table 5-2. Patient Information Fields

Field	*Description*
Patient ID	number used to identify the patient
Accession #	number used to identify the sample
Location	location of the patient

(Continued)

Field	Description
Temperature	temperature of the patient
tHb	total hemoglobin value of the patient
Source	origin of the patient sample
Draw Date	date sample was drawn
Draw Time	time sample was drawn
F_IO_2	fraction of inspired air
Ventilator Flow	flow rate setting on the patient's ventilator
Respiratory Rate	respiration rate per minute of the patient
*p*50	partial pressure of oxygen at which hemoglobin is 50% saturated
Sex	gender of the patient
Birthdate	date patient was born
Physician ID	number used to identify the physician
Operator ID	number used to identify the 800 system operator

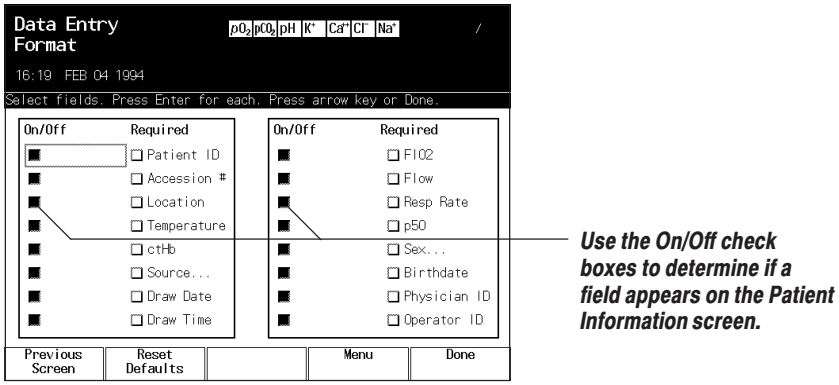
Menu Code

5 2 2

1. Access the Data Entry Format screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **2 Patient Data** and press **Enter**.
   c. Select **2 Data Entry Format** and press **Enter**.

   The Data Entry Format screen appears, as shown in Figure 5-2.

Figure 5-2. Data Entry Format Screen



2. Define another setup function or press **Exit Menu** to return to the Ready screen.
3. Select the fields you want to change:

If you want to . . .	*Then . . .*
make a field appear or not appear	a. Move to the On/Off check box for the field you want. b. Press **Enter** to turn the field on or off. A dark box indicates the field is on. The default value is On. If you turn a field off, it does not appear on the Patient Information screen.
make a field a required field	a. Move to the Required check box for the field you want. b. Press **Enter.** The check box becomes dark, which indicates the field is required. A required field has a ▶ symbol before it on the Patient Information screen.

4. Press **Done**.
5. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you turn all fields off, the Patient Information screen does not appear on the screen during analysis. The system stores results by sequence number.

Defining Custom Panels

Use this procedure to customize a panel that the system will use to analyze a patient sample. You can define up to 5 customized panels.

The system measures only the parameters listed in the panel. You can choose to have a parameter not appear on the panel by turning the parameter off.

NOTE: If you select a parameter to be off, the system does not measure or calculate results during analysis, and the parameter name does not appear on the Results screen or in the printed report. However, a parameter that is turned off is evaluated during quality control testing.

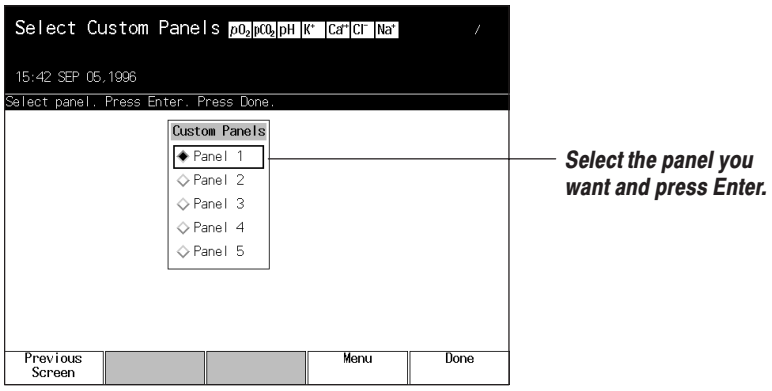
Menu Code

6 ***4*** ***2***

1. Access the Select Custom Panels screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **4 Panels** and press **Enter**.
   c. Select **2 Custom Panel** and press Enter.

   The Select Custom Panels screen appears, as shown in Figure 5-3.

Figure 5-3. Select Custom Panels Screen for an 850 System



2. Select one of panels to configure and press **Done**.

   The Custom Panel screen appears. All parameters are selected.

3. Move to the frame that contains the appropriate parameter. Press **Enter** to turn the parameter on or off.

4. Take the appropriate action.

If you . . .	*Then press . . .*
want to to save the custom panel	**Done** to return to the Ready screen.
do not want to save the custom panel	**Restore Defaults** to clear the screen. Press **Done** to return to the Ready screen.

Selecting a Default Panel

Use this procedure to select the panel that the system will use to analyze a patient sample. You can select default panels from a predefined list or from any defined custom panels. The system measures only the parameters listed in the panel. The system default is All Parameters. Different predefined panels are available on each 800 system, as shown in Table 5-3.

If you want to individually select parameters as the default set of parameters for analysis, refer to *Selecting Parameters for Analysis*, page 5-12.

NOTE: Default panels are used in patient sample analysis only. All parameters are evaluated during quality control analysis.

Table 5-3. Panel Options

System	Panels	Parameters Analyzed
840	All Parameters	pH, pO_2, pCO_2
844	All Parameters	pH, pO_2, pCO_2, tHb, FO_2Hb
	pH/Blood gas	pH, pO_2, pCO_2
	CO-ox	tHb, FO_2Hb
845	All Parameters	pH, pO_2, pCO_2, tHb, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
	pH/Blood gas	pH, pO_2, pCO_2
	CO-ox	tHb, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
850	All Parameters	pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-
	pH/Blood Gas	pH, pO_2, pCO_2
	pH/lytes	pH, Na^+, K^+, Ca^{++}, Cl^-
	Blood gas/lytes	pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-
	pH/Ca^{++}	pH, Ca^{++}
854	All Parameters	pH, pO_2, pCO_2, Na^+, K^+, Cl^-, Ca^{++}, tHb, FO_2Hb
	pH/Blood gas	pH, pO_2, pCO_2
	CO-ox	tHb, FO_2Hb
	pH/lytes	pH, Na^+, K^+, Ca^{++}, Cl^-
	Blood gas/lytes	pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-
	pH/Ca^{++}	pH, Ca^{++}

(Continued)

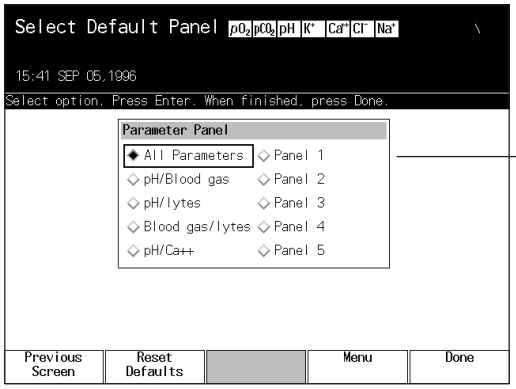
System	Panels	Parameters Analyzed
855	All Parameters	pH, pO_2, pCO_2, Na^+, K^+, Cl^-, Ca^{++}, tHb, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
	pH/Blood gas	pH, pO_2, pCO_2
	CO-ox	tHb, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
	pH/lytes	pH, Na^+, K^+, Cl^-, Ca^{++}
	Blood gas/lytes	pO_2, pCO_2, Na^+, K^+, Cl^-, Ca^{++}
	pH/Ca^{++}	pH, Ca^{++}
860	All Parameters	pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate
	pH/Blood Gas	pH, pO_2, pCO_2
	pH/Blood Gas/lytes	pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-
	pH/lytes/metabolites	pH, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate
	pH/Ca^{++}	pH, Ca^{++}
864	All Parameters	pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, tHb, FO_2Hb
	pH/Blood gas	pH, pO_2, pCO_2
	CO-ox	tHb, FO_2Hb
	pH/lytes/metabolites	pH, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate
	pH/Ca^{++}	pH, Ca^{++}
	pH/Blood gas/lytes/ metabolites	pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate
865	All Parameters	pH, pO_2, pCO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, tHb, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
	pH/Blood gas	pH, pO_2, pCO_2
	CO-ox	tHb, FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
	pH/lytes/metabolites	pH, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate
	pH/Ca^{++}	pH, Ca^{++}
	pH/Blood gas/lytes/ metabolites	pH, pO_2, pCO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate

Menu Code
6 *4* *1*

1. Access the Select Default Panels screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **4 Panels** and press **Enter**.
   c. Select **1 Default Panel** and press **Enter**.

   The Select Default Panel screen appears, as shown in Figure 5-4.

Figure 5-4. Select Default Panel Screen for an 850 System



2. Select the appropriate panel and press **Enter**.

   Custom panels are listed as Panels 1–5. Custom panels are defined during system setup by the system administrator or authorized personnel. Refer to *Defining Custom Panels* on page 5-9.

3. Press **Done** when you finish.

Selecting Parameters for Analysis

Use this procedure to select the default set of parameters you want the system to analyze. If you select a parameter to be off, the system does not measure or calculate results during analysis, and the parameter name does not appear on the Results screen or the printed report. The default value for all parameters is on, except for O_2SAT, O_2CT, and [Qsp/Qt (est,T)].

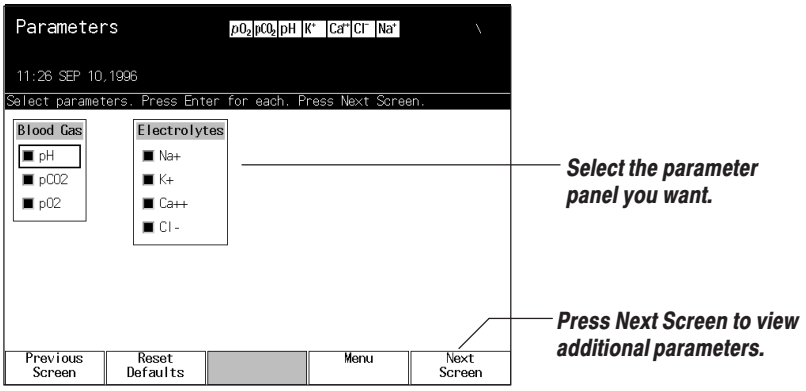
NOTE: Any calculated parameters that rely on another parameter value, which has been selected to be off, are not calculated. However, the parameter name appears on the Results screen, but no value is reported and the parameter name and value do not appear on the printed report.

Menu Code
6 *3*

1. Access the Parameters screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **3 Parameters** and press **Enter**.

   The Parameters screen appears, as shown in Figure 5-5.

Figure 5-5. Parameters Screen for an 850 system



2. Select the parameters.
   a. Move to the frame that contains the appropriate parameter.
   b. Select the parameter that you want and press **Enter**.
   c. Repeat steps a and b for each parameter you want to change.
   d. Press **Next Screen** to access the second screen of parameters.
   e. Repeat steps a and b for each parameter you want to change.
   f. Press **Next Screen** again to access the final screen of parameters.
   g. Repeat steps a and b for each parameter you want to change.
3. Press **Done**.
4. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

When you select a measured parameter to be on, you activate a sensor. Perform a two-point calibration before you analyze a sample.

Selecting Parameter Units

Use this procedure to select the measurement units that the system displays for each parameter. Table 5-4 lists the default and optional measurement units that you can select for the base models and for the base models with a CO-ox module.

Table 5-4. Parameter Measurement Units

Parameter	*Default Units*	*Optional Units*	*System*
pCO_2, pO_2	mmHg	kPa	840, 850, 860
O_2CT, BO_2	mL/dL	mL/L, mmol/L	840, 850, 860

(Continued)

Parameter	Default Units	Optional Units	System
*c*tHb	g/dL	g/L, mmol/L	840, 850, 860
pH	pH	H^+ nmol/L	840, 850, 860
O_2SAT, F_IO_2, sO_2, Hct, Hb Fractions	%	decimal fraction	840, 850, 860
Ca^{++}	mmol/L	mg/dL	850, 860
Glucose	mg/dL	mmol/L	860
Lactate	mmol/L	mg/dL	860

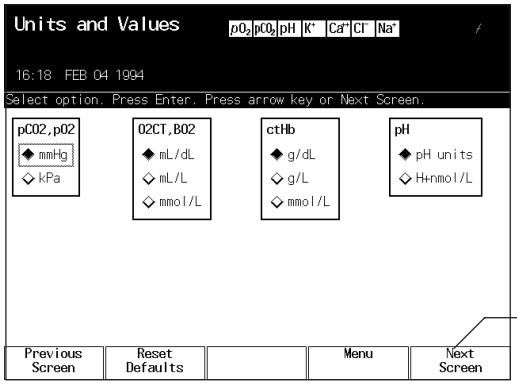
Menu Code

5 ***4***

1. Access the Units and Values screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **4 Units/Values** and press **Enter**.

   The Units and Values screen appears, as shown in Figure 5-6.

Figure 5-6. Units and Values Screen for an 850



Press Next Screen to view additional parameters.

2. Select the measurement units:
   a. Move to the frame that contains the measurement unit you want to change.
   b. Select the unit you want and press **Enter**.
   c. Repeat steps a and b for each measurement unit you want to change.
   d. Press **Next Screen** to view additional parameters.
   e. Repeat steps a and b for each measurement unit you want to change.
3. Press **Done**.
4. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you change parameter units for pH after the system has started to collect data, QC statistics are still computed in the current units.

Defining Parameter Values

Use this procedure to define the values for *c*tHb and *p*50 that the system uses when no value is entered or measured, and to define the value for the O_2 binding factor and *c*tO_2(a-v), which are constants supplied by the system. The system uses these values for certain calculations. Table 5-5 lists the default values and valid ranges for *c*tHb, O_2 binding factor, *p*50, and *c*tO_2(a-v).

Table 5-5. Default Measurement Values

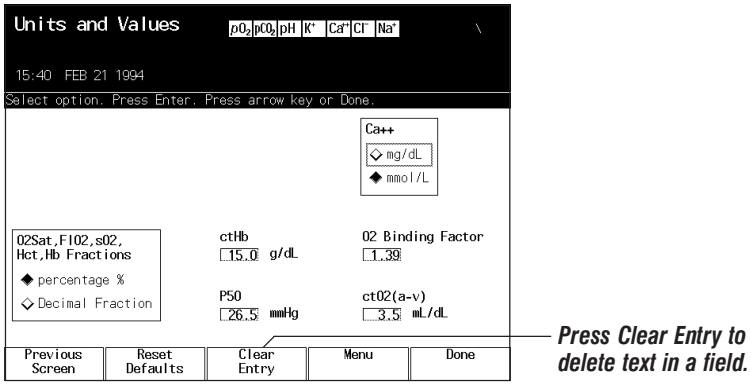
Parameter	*Valid Range*	*Default Value*	*Units*
*c*tHb	2.0 – 25.0	15.0	g/dL
	20 – 250		g/L
	1.2 – 15.5		mmol/L
*p*50	0.0 – 100.0	26.5	mmHg
	0.00 – 13.32		kPa
O_2 Binding	1.35 – 1.39	1.39	
*c*tO_2(a-v)	0.0 – 20.0	3.5	mL/dL
	0 – 200		mL/L
	0.0 – 9.0		mmol/L

Menu Code

5 4

1. Access the Units and Values screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **4 Units/Values** and press **Enter**.
   The first Units and Values screen appears.
2. Press **Next Screen**.
   The second Units and Values screen appears as shown in Figure 5-7.

Figure 5-7. Units and Values Screen for an 850



3. Change the appropriate parameter values:
   a. Move to the field you want to change.
   b. Type in the new value and press **Enter**.
   c. Repeat steps a and b for each parameter value you want to change.
4. Press **Done** when you finish.
5. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you press Done before completing all the fields, the Incomplete Data Entry message box appears. Press **OK** and complete the required fields.

If you type an invalid value in a field and press Done, the Invalid Entry message box appears. Press **OK** and type a valid entry in the field.

Selecting Parameter Names

Use this procedure to select the parameter name (nomenclature) that the system uses to display results on the screen and in reports. Table 5-6 lists the parameter names available for parameters that have more than one acceptable chemical name. Option 2 is the default.

Table 5-6. Parameter Name Options

Option 1	*Option 2*
BEvt	BE(B)
BEvv	BE(ecf)
tCO_2	$ctCO_2$

(Continued)

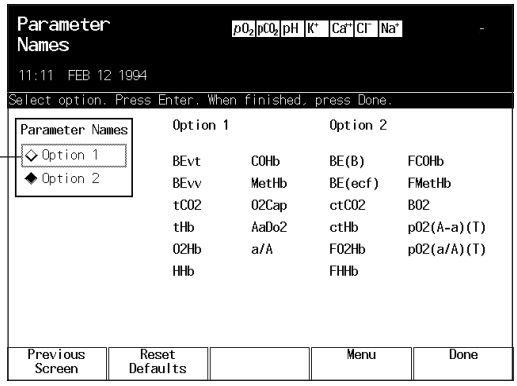
Option 1	Option 2
tHb	*c*tHb
O_2Cap	BO_2
$AaDO_2$	pO_2(A–a)(T)
a/A	pO_2(a/A)(T)

Menu Code

5 5

1. Access the Parameter Names screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **5 Parameter Names** and press **Enter**.
   The Parameter Names screen appears, as shown in Figure 5-8.

Figure 5-8. Parameter Names Screen



Select the option you want and press Enter.

2. Select **Option 1** or **Option 2** and press Enter**.**
3. Press **Done** when you finish.
4. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Defining Reference and Action Ranges

Use this procedure to define the reference and action ranges for each parameter. The system uses reference ranges to determine if a result is outside of the expected range. The system uses action ranges to determine if a result requires immediate action. Each laboratory should establish its own reference and action ranges for the evaluation of patient results. Table 5-7 lists the default values for reference and action ranges for the base models and for the base models with a CO-ox module.

NOTE: The default values for the action range are equal to the measurement range. If you use the default action range values, the system does not flag action range results but instead indicates that the results are out of measurement range. Change the action range values to have the system flag action range results.

Table 5-7. Default Reference and Action Range Values

Parameter	*Units*	*Reference Range*	*Action Range*	*System*
pH		7.350 – 7.450*	6.000 – 8.000	840, 850, 860
pCO_2	mmHg	35.0 – 45.0*	5.0 – 250.0	840, 850, 860
pO_2	mmHg	75.0 – 100.0†	0.0 – 800.0	840, 850, 860
Na^+	mmol/L	135.0 – 148.0‡	70.0 – 200.0	850, 860
K^+	mmol/L	3.50 – 5.30*	0.50 – 20.00	850, 860
Ca^{++}		1.13 – 1.32‡	0.25 – 5.00	850, 860
Cl^-	mmol/L	98 – 106*	40 – 160	850, 860
Glucose	mg/dL	66 – 93§	10 – 999	860
Lactate	mmol/L	0.5 –2.0*§	0.0 – 30.0	860

* Tietz NW ed. Fundamentals of Clinical Chemistry. 3rd ed. Philadelphia: WB Saunders, 1987; 864-891.

† Weisberg HF. Acid-Base pathophysiology in the neonate and infant. Annals of Clinical and Laboratory Science 1982; 12(4)249.

‡ Lentner C ed. Geigy scientific tables. Vol 3, 8th ed. Basle: Ciba-Geigy Ltd., 1984; 82-83.

§ Toffaletti et al., Clinical Chemistry, 38/12; 2430-2434, 1992

‖ Sabata V, Stubbe P, Wolf H. Energy metabolism in the premature fetus. Biology Neonate. 1971; 19:299.

Table 5-8 lists additional default values available on systems with a CO-ox module.

Table 5-8. CO-ox Module Default Reference and Action Range Values

Parameter	*Units*	*Reference Range*	*Action Range*
tHb	g/dL	12.0 – 18.0*	2.0 – 27.0
ctO_2	mL/dL	15.0 – 23.0†	0.0 – 40.0
BO_2	mL/dL	16.0 – 24.0†	0.0 – 40.0
sO_2	%	92.0 – 98.5	–99.9 – 999.9

(Continued)

Parameter	Units	Reference Range	Action Range
FO_2Hb	%	94.0 – 97.0†	–99.9 – 999.9
FCOHb	%	0.5 – 1.5†	–99.9 – 999.9
FMetHb	%	0.0 – 1.5†	–99.9 – 999.9
FHHb	%	0.0 – 5.0	–99.9 – 999.9

* Tietz NW ed. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders, 1987; 864-891.

† Weisberg HF. Acid-Base pathophysiology in the neonate and infant. Annals of Clinical and Laboratory Science 1982; 12(4)249.

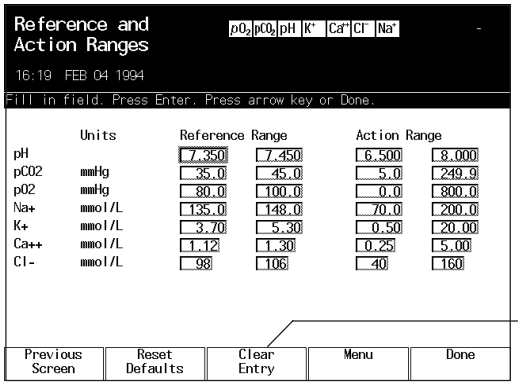
Menu Code

5 2 1

1. Access the Reference and Action Ranges screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **2 Patient Data** and press **Enter**.
   c. Select **1 Ref/Action Ranges** and press **Enter**.

   The Reference and Action Ranges screen appears, as shown in Figure 5-9.

Figure 5-9. Reference and Action Ranges Screen for an 850



2. Move to the field that you want to change.
3. Type the new value and press **Enter**.
4. Repeat steps 2 and 3 for any other values that you want to change.
5. Press **Done**.
6. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you press Done before completing all required fields, the Incomplete Data Entry message box appears. Press **OK** and complete the required fields.

If you type an invalid value in a field and press Done, the Invalid Range message box appears. Press **OK** and type a valid entry in the field.

Selecting Printing Options

Use this procedure to select automatic printing, number of copies, and printer type for the following reports:

- patient sample reports
- QC reports
- calibration reports

You select options separately for each type of report. Table 5-9 lists the available report printing options.

Table 5-9. Report Printing Options

Option	*Description*
Roll Printer	Lets you turn the roll printer on or off. When you turn the roll printer off, it is off for all report types. The default is On.
Paper Spool	Lets you turn the printer paper spool on or off. The default is On.
Copies	Lets you select the number of copies the system prints automatically at the end of analysis. The default is 1. Entry values are 1 – 3. **NOTE:** This option is available only when the roll printer is selected.
Auto Print	Lets you control whether the system prints a report automatically at the end of analysis. The default setting is On.
Printer	Lets you select the printer (roll, line, and ticket) the system uses to print reports. The default is roll printer. You can select more than one printer, but you cannot select line printer for calibration reports, or ticket printer for QC reports.

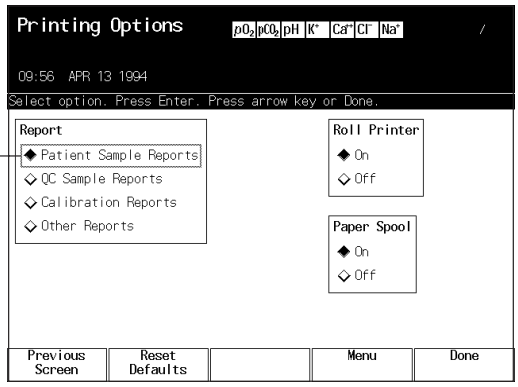
Menu Code

5 7

1. Access the Printing Options screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **7 Printing Options** and press **Enter**.

   The Printing Options screen appears with the cursor in the Report frame, as shown in Figure 5-10.

Figure 5-10. Printing Options Screen



Select a report type and press Done. Then select the report printing options.

2. Select the type of report required.
3. Press **Done**.

   The second Printing Options screen appears.
4. Select the printing options you want from this screen. Press **Enter** after your selections. Refer to Table 5-9 for the list of options.
5. Press **Done**.

   A message appears prompting you to set up another report.

If you . . .	*Then press . . .*
want to select options for another report	**Yes**. The Printing Options screen reappears. Repeat steps 2 thru 5 to select options for another report.
do not want to select options for another report	**No**. The Menu screen appears.
want to remain at the current screen	**Cancel**. The cursor returns to the last field you completed.

6. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Defining the Printer Report Format

Use this procedure to do the following:

- Select the report format that the system uses to print the patient sample results.
- Select the report formats for roll and line printers.
- Print a copy of each report format.
- Create four lines of information to appear at the top of each report. You need an alphanumeric keyboard to type the information.

The 800 systems provide a variety of printed report formats. Refer to Appendix F, *Printed Reports*, for an example of each report format.

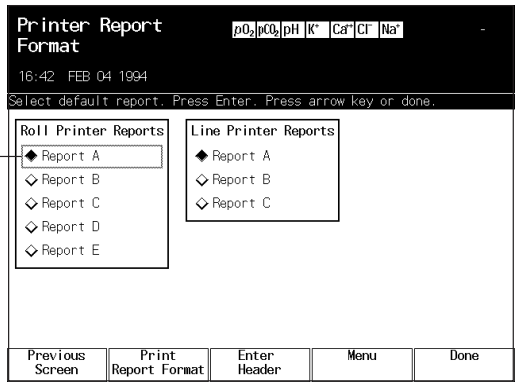
Menu Code

5 ***3***

1. Access the Printer Report Format screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **3 Report Formats** and press **Enter**.

   The Printer Report Format screen appears, as shown in Figure 5-11.

Figure 5-11. Printer Report Format Screen



Select the format you want and press Enter.

2. Select the format you require and press **Enter**.

NOTE: You can select a report format for the roll printer and, if a line printer is connected, for a line printer.

3. You can print a copy of a report to view the format and create lines of information to appear in the header of the report:

If you want to . . .	*Then . . .*
print a report	a. Select the report type you want. b. Press **Print Report Format**. A copy of the report format prints on the printer you selected.
create information lines for a report	a. Press **Enter Header**. The Enter Header Information box appears. b. Type the text (up to 25 characters) for each line and press **Enter**. c. Press **Save** when you finish.

4. Press **Done** when you finish.
5. Define another setup function or press **Exit Menu** to return to the Ready screen.

Turning Off the Roll Printer

Use this procedure to turn the roll printer on and off. When you turn the roll printer off, it is off for all reports. You cannot turn the roll printer on for a specific report type.

The default value for the roll printer is On.

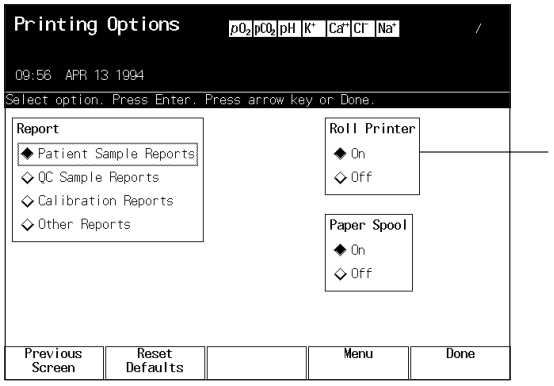
Menu Code

5 ***7***

1. Access the Printing Options screen from the Menu screen:
   a. Press **5 Operating Setup** and press **Enter**.
   b. Press **7 Printing Options** and press **Enter**.

   The Printing Options screen appears, as shown in Figure 5-12.

Figure 5-12. Printing Options Screen



Move to the Roll Printer frame and select On or Off.

2. Move to the Roll Printer frame.
3. Select **On** or **Off** and press **Enter**.
4. Press **Done**.

   The next Printing Options screen appears.
5. Press **Done** again.
6. You are prompted to set up another report.

If you . . .	***Then . . .***
want to set up another report	press **Yes**. The first Printing Options screen appears.
do not want to set up another report	press **No**. The Menu screen appears.
want to return to the second Printing Options screen	press **Cancel**. The second Printing Options screen appears.

Turning Off the Paper Spool

Use this procedure to turn the paper spool on or off. The paper spool automatically winds the roll printer paper as the reports print. The default value is On.

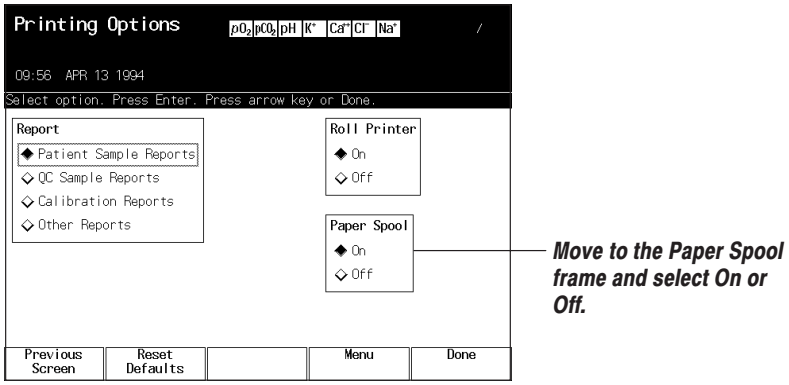
Menu Code

5 ***7***

1. Access the Printing Options screen from the Menu screen:
   a. Press **5 Operating Setup** and press **Enter**.
   b. Press **7 Printing Options** and press **Enter**.

   The Printing Options screen appears, as shown in Figure 5-13.

Figure 5-13. Printing Options Screen



2. Move to the Paper Spool frame.
3. Select **On** or **Off** and press **Enter**.
4. Press **Done**.

   The next Printing Options screen appears.
5. Press **Done** again.
6. You are prompted to set up another report.

If you . . .	*Then . . .*
want to set up another report	press **Yes**. The first Printing Options screen appears.
do not want to set up another report	press **No**. The Menu screen appears.
want to return to the second Printing Options screen	press **Cancel**. The second Printing Options screen appears.

Selecting Password Protection

Use this procedure to select sample analysis and menu functions for password protection. When you password protect sample analysis or menu functions, operators must enter a password to access the protected function.

Select the Sample Analysis option to password protect the system from unauthorized use. Operators must then enter a valid operator password to analyze samples and to perform any other system function. You can define passwords for up to 500 operators. Refer to *Defining Operator Passwords*, page 5-27, to define passwords for authorized operators.

Select the menu options you want password protected to prevent unauthorized changes by operators. Operators must then enter the valid menu options password to access the protected menus. For example, you can password protect the Operating Setup menu. Operators must then enter the menu options password to access the Operating Setup menu. They can still access other menu functions without a password. Refer to *Defining the Menu Options or Supervisor Password*, page 5-29, to define the menu options password.

Menu Code

6 ***7*** ***4***

1. Access the Password Protection screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **7 Security Setup** and press **Enter**.
   c. Select **4 Password Protection** and press **Enter**.

   NOTE: You must enter the supervisor password to access the Password Protection screen. The default supervisor password is 12345. If you already defined the supervisor password, you must enter that password.

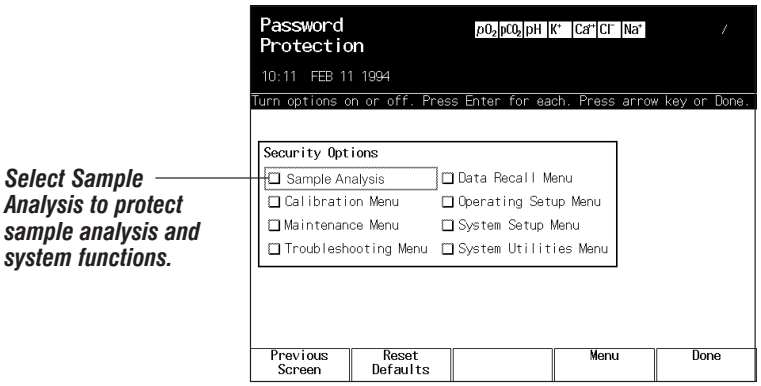
   A message appears prompting you to enter the supervisor password.

2. Type the supervisor password in the Password field and press **OK**.

   As you type the password, the password does not appear on the screen.

   The Password Protection screen appears, as shown in Figure 5-14.

Figure 5-14. Password Protection Screen



Select Sample Analysis to protect sample analysis and system functions.

3. Select the functions that you want to protect and press **Enter**.

   Any combination of menu options can be password protected.

   The password protection default value for all functions is off.

4. Press **Done**.

5. Define the appropriate passwords.

If you selected . . .	*Then . . .*
Sample Analysis for password protection	define the operator passwords, as described in *Defining Operator Passwords*, page 5-27.
any menu options for password protection	define the menu options password, as described *Defining the Menu Options or Supervisor Password*, page 5-29.

Defining Operator Passwords

Use this procedure to define new operator passwords and to edit or delete existing passwords. You can assign passwords for up to 500 operators.

When an operator enters a password to access system functions, the system automatically enters the operator's ID in the Patient and QC Data Entry forms and, when recording maintenance tasks, the Maintenance Task Done dialog box. The operator ID also prints on the patient sample, QC sample, and maintenance log reports.

If you want to protect access to sample analysis, select Sample Analysis for password protection. Refer to *Selecting Password Protection*, page 5-26, if you have not already selected Sample Analysis for password protection.

Menu Code

6 ***7*** ***3***

1. Access the Operator Passwords screen from the Menu screen:

   a. Select **6 System Setup** and press **Enter**.

   b. Select **7 Security Setup** and press **Enter**.

   c. Select **3 Operator Passwords** and press **Enter**.

   NOTE: You must enter the Supervisor Password to access the Operator Passwords screen. The default supervisor password is 12345. If you already defined the supervisor password, you must enter that password.

   A message appears prompting you to enter the supervisor password.

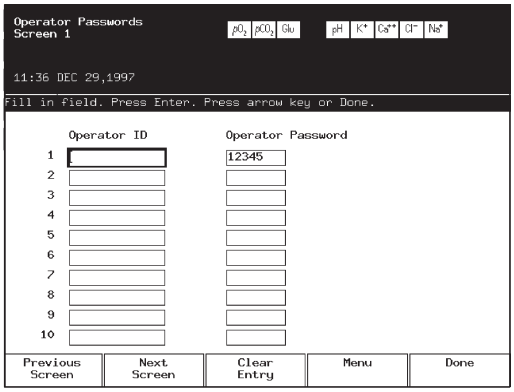
2. Type the supervisor password in the Password field and press **OK**.

   As you type the password, the password does not appear on the screen.

   The Operator Passwords screen appears, as shown in Figure Figure 5-15.

NOTE: The first operator password has a default value of 12345. To ensure that there is always at least one active operator password, you can edit the default password, but you cannot delete it.

Figure 5-15. Operator Passwords Screen



NOTE: If you want to define only one operator password for all operators to use, enter the password you want and leave the Operator ID field blank. The operator ID in the Patient and QC Data Entry forms and the Maintenance Task Done dialog box will be blank. The operator ID on the patient sample, QC sample, and maintenance log reports will also be blank.

3. Take the appropriate action.

If you want to . . .	*Then . . .*
define a new operator password	a. Type the ID in the Operator ID field and press **Enter**. b. Type the password in the Operator Password field and press **Enter**.
edit a password or ID	retype the ID in the Operator ID field or the password in the Operator Password field and press **Enter.**
delete a password or ID	press **Clear Entry** to delete text in the Operator ID or Operator Password field.

Bayer Diagnostics recommends that you keep a record of operator IDs and passwords to help you track and manage assigned operator passwords. Operator Password Screens are numbered 1 to 50 and operator fields are numbered 1 to 10 on each screen to help you list the passwords.

4. Press **Done**.
5. Define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

Operator IDs can contain 1 to 13 alphanumeric characters and can include spaces.

Operator passwords can contain 1 to 8 alphanumeric characters, can include spaces, and are case sensitive.

If you enter an operator ID without an operator password, the system does not accept the entry.

When you have entered 10 operator passwords, press Next Screen to continue entering passwords. At Screen 50, Next Screen takes you to Screen 1. At Screen 1, Previous Screen takes you to Screen 50.

Defining the Menu Options or Supervisor Password

Use this procedure to define or edit the supervisor password or the password required to access menu functions.

The supervisor password must be used to access screens in Security Options and can be used to access sample analysis.

Define a menu options password only if you want to password protect access to menu functions. Refer to *Selecting Password Protection*, page 5-26, to select menu options for password protection.

Menu Code

6 7 1

1. Access the Set Passwords screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **7 Security Setup** and press **Enter**.
   c. Select **1 Set Passwords** and press **Enter**.

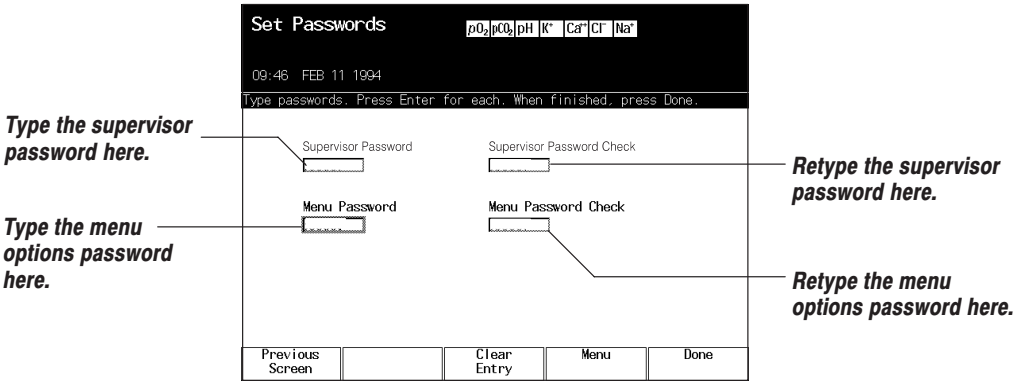
   NOTE: You must enter the supervisor password to access the Set Passwords screen. The default supervisor password is 12345. If you already defined the supervisor password, you must enter that password.

   A message appears prompting you to enter the supervisor password.
2. Type the supervisor password in the Password field and press **OK**.

   As you type the password, the password does not appear on the screen.

   The Set Passwords screen appears, as shown in Figure 5-16.

Figure 5-16. Set Passwords Screen



NOTE: You must enter values into both the Supervisor Password and the Menu Password fields. If you do not use or uniquely define one or the other password, you can enter the default password. The default for both passwords is 12345.

3. Enter the supervisor or menu options password you want to use:
   a. Type the password in the Supervisor Password field and press **Enter**.
   b. Type the same password in the Supervisor Password Check field and press **Enter**.

      You can use the same password for the supervisor and menu passwords or create a different password for each.
   c. Type the password in the Menu Password field and press **Enter**.
   d. Type the same password in the Menu Password Check field and press **Enter**.
4. Press **Done**.

   If the Password Check you typed does not match the Password, the system prompts you to try again. Press **OK** and retype the Password Check.
5. Define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you press Done before you assign passwords, a message appears prompting you to enter a password. Press **OK**.

You can enter up to 8 alphanumeric characters including the dash in the password field.

Changing the Date and Time

Use this procedure to change the date and time. Table 5-10 lists the date and time formats that you can use.

Table 5-10. Date and Time Formats

Item	*Format*	*Example*
Date	MM/DD/YY	06/24/94 **NOTE:** The date that appears on reports and on the screen uses three letters for the month, for example, Jun 24 1994.
	DD/MM/YY	24/06/94 **NOTE:** The date that appears on reports and on the screen uses three letters for the month, for example, 24 Jun 1994.
	YY/MM/DD	94/06/24 **NOTE:** The date that appears on reports and on the screen is completely numeric, for example, 1994.06.24.
Time	HH:MM (24-hour clock)	18:23 (6:23 p.m.)

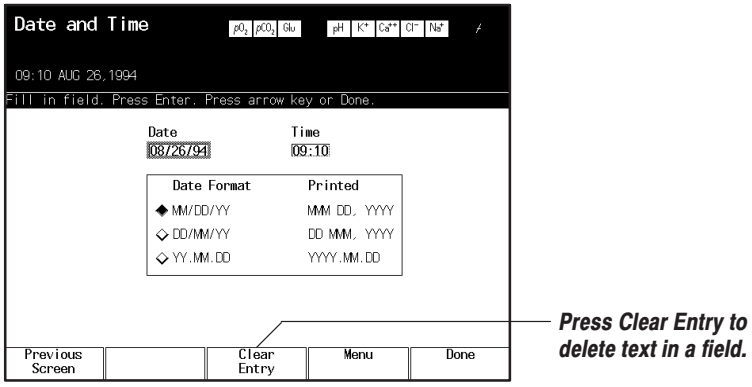
Menu Code

6 ***1***

1. Access the Date and Time Setup screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **1 Date and Time** and press **Enter**.

   The Date and Time Setup screen appears, as shown in Figure 5-17.

Figure 5-17. Date and Time Setup Screen



2. Change the date and time.

If you want to change the . . .	*Then . . .*
Date	a. Move the cursor to the Date field. b. Type the month, date, and year in the selected format. Press **Enter** after you complete the field. The cursor moves to the Time field.
Time	a. Move the cursor to the Time field. b. Type the hour and minutes in the format, HH:MM. You can enter 0 – 23 hours and 0 – 59 minutes. c. Press **Enter** after you complete the field.
Date Format	a. Move the cursor to the required format. b. Press **Enter.** The date is reformatted, if necessary.

3. Press **Done** when you finish.

   If you changed the date or format, the Updating Database message box appears.

4. Define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you press Done before completing all required fields, the Incomplete Data Entry message box appears. Press **OK** and complete the required fields.

If you type an invalid value in a field and press Done, the Invalid Entry message box appears. Press **OK** and type a valid entry in the field.

To type a single number in a date or time field, you must precede the number with a zero. For example, to enter June as the date, you must enter 06 in the month field.

Selecting Languages

Use this procedure to select the language that the system uses to present information on the screen and in printed reports.

Menu Code

8 ***3***

1. Access the Service Setup screen from the Menu screen:
   a. Select **8 Service Setup** and press **Enter**.
   b. Select **3 Language Selection** and press **Enter**.
2. Select the appropriate language and press **Enter**.
3. Press **Done**.
4. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Changing the Auto Clean Time

Use this procedure to change the time when the system performs the automatic cleaning of the reagent manifold. Auto Clean occurs once every 24 hours. The default time is 0200.

On the first day of the month, the system also prints out final statistical summary reports of the previous month's QC data at the time of the Auto Clean.

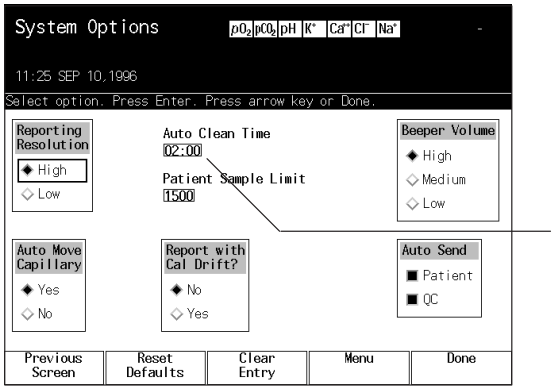
Menu Code

6 ***5***

1. Access the System Options screen from the Menu screen:
   a. Press **6 System Setup** and press **Enter**.
   b. Press **5 Systems Options** and press **Enter**.

   The System Options screen appears, as shown in Figure 5-18.

Figure 5-18. System Options Screen for an 850



2. Move to the Auto Clean Time field.
3. Type the hour and minutes in the format, HH:MM. You can enter 0 – 23 hours and 0 – 59 minutes.
4. Press **Done** when you finish.
5. Define another setup function or press **Exit Menu** to return to the Ready screen.

Scheduling Maintenance Tasks

Use this procedure to:

- define the start date for scheduling maintenance on your system
- increase or decrease the frequency of the maintenance tasks

Menu Code

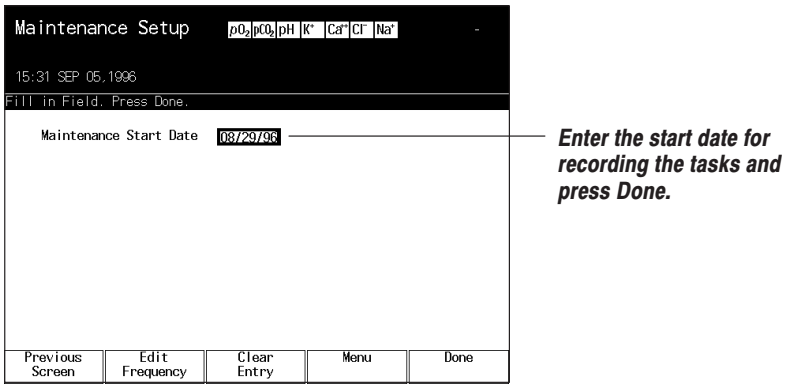
6 ***2***

1. Access the Maintenance Setup screen from the Menu screen:
   a. Press **6 System Setup** and press **Enter**.

b. Press **2 Maintenance Tasks** and press **Enter**.

The Maintenance Setup screen appears, as shown in Figure 5-19.

Figure 5-19. Maintenance Setup Screen



2. Enter the start date for recording the maintenance tasks.

   Tasks become due on midnight of the scheduled date. For example, weekly tasks are due every 7 days after the start date, monthly tasks are due every fourth week after the start date.

3. Take the appropriate action.

If you want to . . .	*Then . . .*
keep the existing maintenance schedule	go to step 10.
change the frequency of a maintenance task	go to step 4.

4. Select **Edit Frequency**.
5. Use the arrow keys to select a task.
6. Select **Select Frequency**.
7. Use the arrow keys to select a frequency for the task.
8. Select **OK** to change the frequency or select **Cancel** to return to the Maintenance Schedule screen.
9. Repeat steps 5 through 8 to change the frequency of another task or go to step 10.
10. Press **Done** to return to the Main menu screen.

Defining the Size of Patient Sample Database

Use this procedure to define the number of patient samples that can be stored on your hard disk. You have the option of maximizing your patient sample database and storing up to 5,000 samples on your hard disk or minimizing the database by reducing the number of stored samples.

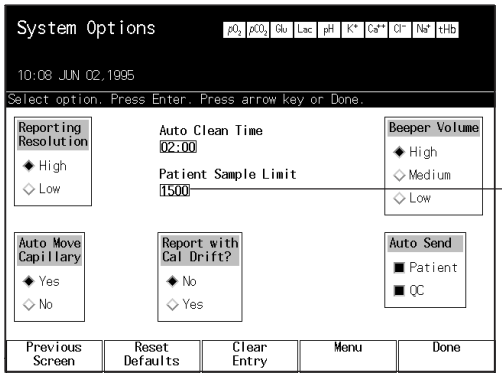
Menu Code

6 ***5***

1. Access the System Options screen from the Menu screen.
   a. Select **6 System Setup** and press **Enter**.
   b. Select **5 System Options** and press **Enter**.

   The System Options screen appears, as shown in Figure 5-20.

Figure 5-20. System Options Screen for an 850



Highlight the Patient Sample Limit field.

2. Highlight the Patient Sample Limit field.
3. Type a number from 100 to 5000.

   The default is 1500. Set the limit slightly higher than the usual number of samples stored on the system before your scheduled backup. The system overwrites the oldest records on the system once the number reaches the specified limit.

   For example, if your laboratory averages 250 samples per week, and has a weekly backup schedule, you could set the patient sample limit to 350. This reduces the database yet ensures that no data is overwritten before the scheduled backup.
4. Press **Done** when you finish.
5. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Adjusting the Beeper Volume

Use this procedure to adjust the beeper volume. You can select a high, medium, or low volume. The default value is high.

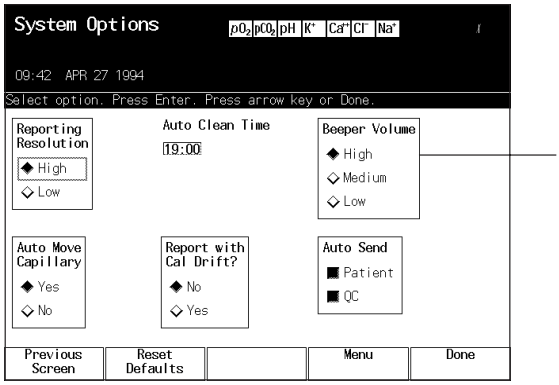
Menu Code

6 5

1. Access the System Options screen from the Menu screen:
   a. Press **6 System Setup** and press **Enter**.
   b. Press **5 Systems Options** and press **Enter**.

   The System Options screen appears, as shown in Figure 5-21.

Figure 5-21. System Options Screen for an 850



2. Move to the Beeper Volume frame.
3. Select a volume level and press **Enter**.
4. Press **Done** when you finish.
5. Define another setup function or press **Exit Menu** to return to the Ready screen.

Controlling Capillary Sample Movement

Use this procedure to control the way the system moves capillary samples to the measurement module. You can choose to move the samples manually or to have the system move them automatically.

Table 5-11. Auto Move Capillary Options

Option	Description
Yes	The system moves capillary samples automatically to the measurement module. The default value is Yes.
No	The operator moves capillary samples to the measurement module by turning the sample pump.

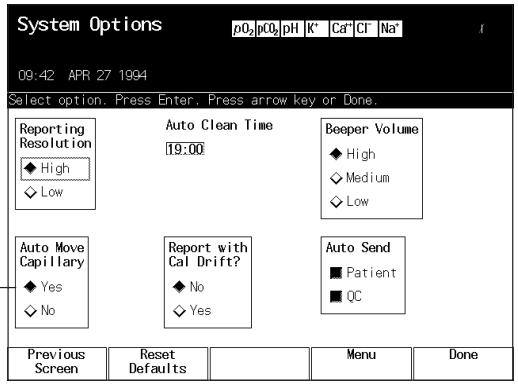
Menu Code

6 ***5***

1. Access the System Options screen from the Menu screen:
   a. Press **6 System Setup** and press **Enter**.
   b. Press **5 Systems Options** and press **Enter**.

   The System Options screen appears, as shown in Figure 5-22.

Figure 5-22. System Options Screen for an 850



Move to the Auto Move Capillary frame and select Yes or No.

2. Move to the Auto Move Capillary frame.
3. Select **Yes** or **No** and press **Enter**.
4. Press **Done**.
5. Define another setup function or press **Exit Menu** to return to the Ready screen.

Defining Automatic Transmission of Results

Use this procedure to select automatic transmission of patient sample results directly to an LIS, HIS, or data management system. You can use this option only if your 800 system is connected to an LIS or data management system. Refer to *Selecting Automatic Transmission of QC Results*, page 5-55, for the procedure to define auto send for QC results.

Table 5-12. Auto Send Patient Sample Options

Option	Description
On	The system automatically sends patient sample results to an LIS or data management system. The default setting is On.
Off	Results are not automatically transmitted. The operator must press **Send** to transmit results or press **Do Not Send** to prevent transmission of results.

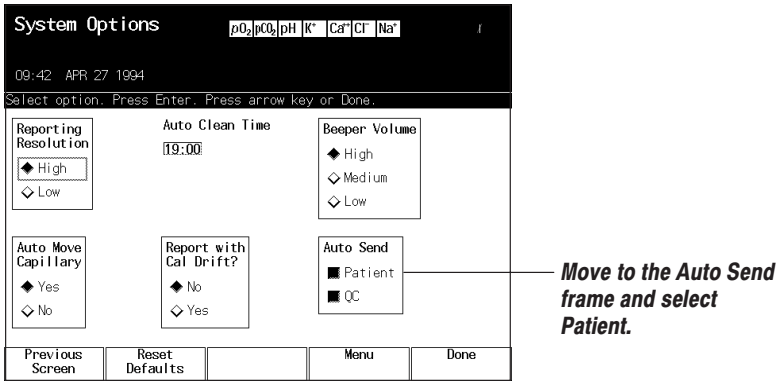
Menu Code

6 ***5***

1. Access the Systems Options screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **5 Systems Options** and press **Enter**.

   The System Options screen appears, as shown in Figure 5-23.

Figure 5-23. System Options Screen for an 850



2. Move to the Auto Send frame.
3. Select **Patient** and press **Enter**.

   A dark box indicates the option is on.
4. Press **Done**.
5. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Defining Significant Digits

Use this procedure to define the number of significant digits reported for certain primary parameters. Table 5-13 lists the parameters that have high and low resolution options. The default value is high.

Table 5-13. Reporting Resolution Options

Option	Parameter	Units	Significant Digits
Low	pH		0.01
	H^+	nmol/L	1
	pCO_2	mmHg	1
		kPa	0.1
	pO_2	mmHg	1
		kPa	0.1
High	pH		0.001
	H^+	nmol/L	0.1
	pCO_2	mmHg	0.1
		kPa	0.01
	pO_2	mmHg	0.1
		kPa	0.01

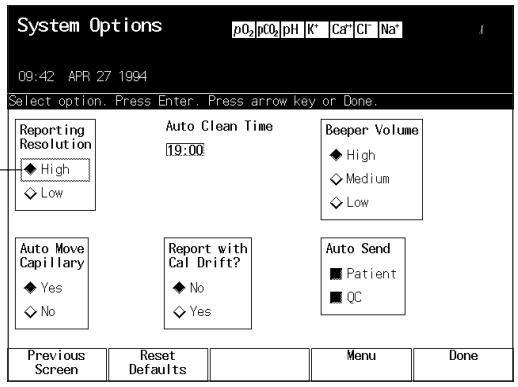
Menu Code

6 ***5***

1. Access the System Options screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **5 System Options** and press **Enter**.

   The System Options screen appears with the cursor in the Reporting Resolution frame, as shown in Figure 5-24.

Figure 5-24. System Options Screen for an 850



Move to the Reporting Resolution frame and select High or Low.

2. Select **High** or **Low** and press **Enter**.
3. Press **Done**.
4. Define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

The option that you select for the Reporting Resolution is saved with each patient and QC sample. If you recall the sample data later and have changed the resolution, the system prints the report using the resolution selected when the sample was saved.

Reporting Results with Calibration Drift

Use this procedure to define the way the system processes patient sample results when a sensor is out of calibration. When the system detects a sensor that has excessive calibration drift, it cannot analyze samples until the drift is corrected. By selecting Yes for Report Results with Cal Drift, you have the option to let the system analyze a sample when a sensor is out of calibration.

Table 5-14. Report Results with Cal Drift Options

Option	*Description*
Yes	The system analyzes the sample and logs the event in the status log. The printed report contains the message, not in calibration.
No	A D2 code appears and the affected sensor is turned off. Analysis continues but no results are generated for the affected sensor. The default value is No.

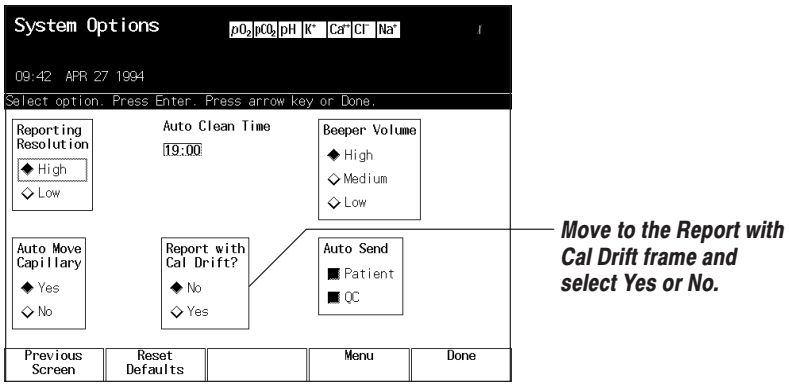
Menu Code

6 5

1. Access the System Options screen from the Menu screen:
   a. Press **6 System Setup** and press **Enter**.
   b. Press **5 Systems Options** and press **Enter**.

   The System Options screen appears, as shown in Figure 5-25.

Figure 5-25. System Options Screen for an 850



2. Move to the Report with Cal Drift frame.
3. Select **Yes** or **No** and press **Enter**.
4. Press **Done**.

If you selected . . .	*Then . . .*
Yes	A password message appears prompting you to enter the menu password and an operator ID. a. Type the menu password and operator ID and press **Enter**. b. Press **OK**. The Menu screen appears.
No	The Menu screen appears.

5. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Defining Correlation Coefficients

Use this procedure to define correlation coefficients. Correlation coefficients allow you to adjust the patient results from an 800 system to match the patient results from another system. You can specify correlation coefficients for slope and offset (y-intercept). Refer to Appendix G, *Correlation Adjustment*, for the procedure to determine correlation coefficients. Table 5-15 describes the slope and offset correlation values.

Table 5-15. Correlation Coefficient Values

Coefficient	*Default Values*	*Definition*
Slope	1.0	Slope of the line for the method you want the 800 system to match.
Offset	0.0	Difference between the 800 system value and the method you want to match.

Table 5-16 lists the correlation coefficient ranges for the listed base models and base models with CO-ox module.

Table 5-16. Correlation Coefficient Ranges

Parameter	*Slope Range*	*Offset Range*	*System*
pH	0.8 – 1.2	±9.9	840, 850, 860
pCO_2	0.8 – 1.2	±99	840, 850, 860
pO_2	0.8 – 1.2	±99	840, 850, 860
Na^+	0.8 – 1.2	±99	850, 860
K^+	0.8 – 1.2	±99	850, 860
Ca^{++}	0.8 – 1.2	±99	850, 860
Cl^-	0.8 – 1.2	±99	850, 860
Glucose	0.8 – 1.2	±99	860
Lactate	0.5 – 1.2	±99	860
tHb	0.8 – 1.2	±99	base model with CO-ox module

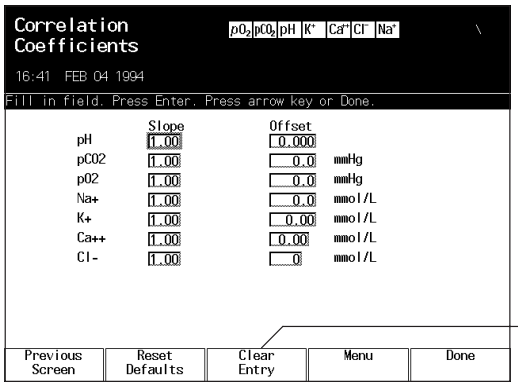
Menu Code

5 8

1. Access the Correlation Coefficients screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **8 Correlation** and press **Enter**.

   The Correlation Coefficients screen appears, as shown in Figure 5-26.

Figure 5-26. Correlation Coefficients Screen for an 850



2. Type the slope and offset values you want for each parameter.
3. Press **Done** when you finish.
4. Define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you press Done before completing all the fields, the Incomplete Data Entry message appears. Press **OK** and complete the required fields.

If you type an invalid value in a field and press Done, the Invalid Entry message box appears. Press **OK** and type a valid entry in the field.

pH values on this screen are always expressed in pH units and not in nmols/L.

Printing the Setup Report

Use this procedure to print the setup report. The setup report contains a record of the setup options selected on your 800 system. Bayer Diagnostics recommends that you print the setup report when you change a setup parameter or value. The report is a record of your setup definitions which can be used later when you want to make another change.

Menu Code

5 ***9***

1. Access the Print Setup Report screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **9 Print Setup Report** and press **Enter**.

   The report takes 1 to 2 minutes to print.
2. When the report finishes printing, press **Exit Menu** to return to the Ready screen.

Defining QC Options

This section describes procedures for the following QC options:

- creating new QC setup files
- editing QC files
- turning QC Auto Identity on and off
- turning Auto Accept QC on and off
- turning QC Auto Send on or off
- printing a QC setup report

QC Setup

Each QC file can store the following information:

- file identification information
- results for the last 150 QC samples
- cumulative statistics, such as the mean, standard deviation, and coefficient of variation
- total number of samples

When you create a new QC setup file, you enter the information shown in Table 5-17.

Table 5-17. QC File Information

Field	*Description*
QC ID	number that identifies the QC material
level	number that describes the level of QC material
lot number	number that identifies the lot of QC material
expiration date	date after which you cannot use the QC material

Bayer Diagnostics Service Representatives use File 13 to store data during service calls.

Creating New QC Files

Use this procedure when you first create a new QC file. The system uses QC files to store results from QC sample analyses. You can use this QC information to create reports summarizing QC results.

NOTE: If you have an existing QC file and want to change to a new lot of QC material, refer to *Editing QC File Setup*, page 5-49.

Menu Code

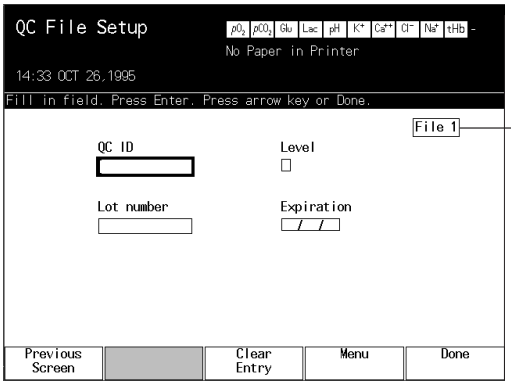
5 ***1*** ***1***

1. Access the QC Files screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **1 QC Setup** and press **Enter**.
   c. Select **1 QC Files** and press **Enter**.
2. Select the file number you want to create and press **Enter**.

   NOTE: You cannot select File 13 as a QC file.
3. Press **Done**.

   The QC File Setup screen appears as shown in Figure 5-27.

Figure 5-27. QC File Setup Screen for an 860



This field displays the file number that you selected.

4. Complete the QC data form:

If you use . . .	*Then . . .*
the keypad	type the QC ID, level, lot number, and expiration date. Press **Enter** after you complete each field.
the optional bar code scanner	scan the QC Catalog and QC Lot/Expiration bar codes from QC Expected Values.

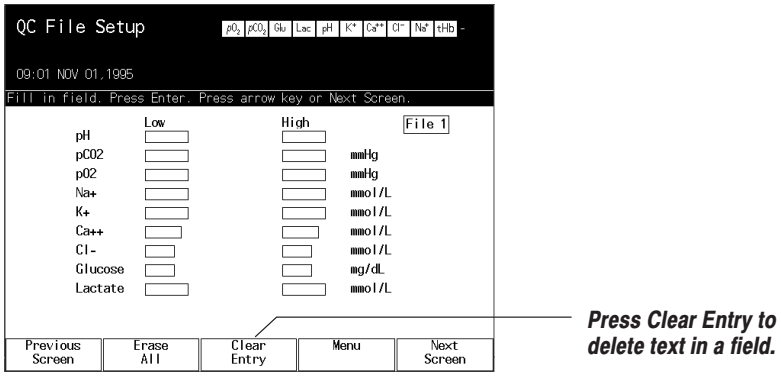
5. Press **Done** when you finish.

   A message appears prompting you to delete the current QC file setup data.

6. Press **Yes**.

   The QC File Setup screen appears with all data fields empty, as shown in Figure 5-28.

Figure 5-28. QC File Setup (Ranges) Screen for an 860



7. Complete the form.

If you use . . .	*Then . . .*
the keypad	type the low and high target limits for each parameter. Press **Enter** after you complete each field.
the optional bar code scanner	scan the target range bar code for each parameter from QC Expected Values. If you scan the wrong bar code, a message appears prompting you to scan the correct parameter bar code. Press **OK** and continue.

   When you complete both fields for a parameter, the system automatically calculates the target value and the action range.

8. If a second screen of parameters exists, press **Next Screen** and enter values on that screen.

9. Press **Done**.

   A message appears prompting you to set up another QC file.

If you want to . . .	*Then press . . .*
save your entries and create another QC file	**Yes**. The QC File screen appears. Continue with step 2.
save your entries and you do not want to create another file	**No**. The Menu screen appears. Define another setup function or press **Exit Menu** to return to the Ready screen.
return to the QC File Setup (ranges) screen	**Cancel**. The cursor returns to the last field you completed.

Procedural Notes

If you press Done before you complete both the low and high fields for a parameter, a message appears telling you the empty field is an invalid range. Press **OK**. Complete the field. If any other incomplete fields exist, the cursor moves to those fields.

If you press Menu before you press Done, a message appears prompting you to save your entries.

If you want to . . .	*Then press . . .*
save your entries	**Yes**. The Menu screen appears.
delete your entries	**No**. The Menu screen appears.
return to the screen	**Cancel**. The cursor returns to the last field you completed.

Editing QC File Setup

Use this procedure to edit QC setup information in an existing QC file under one of the following circumstances:

- When you change QC lots, you want to replace the old QC file information with the new lot information.
- You want to change the high and low range values for a parameter.

If you are creating a QC file for the first time, refer to *Creating New QC Files*, page 5-46.

NOTE: During this procedure, if you are changing QC lots, you must delete the existing QC data stored in the file. If you want to save a copy of the data, archive the file to a diskette before performing this procedure. Refer to *Archiving QC Data*, page 5-68, for more information.

When you change QC lots, replace the information shown in Table 5-18 with the data from the new QC material.

Table 5-18. QC File Information

Field	*Description*
QC ID	number that identifies the QC material
level	number that describes the level of QC material
lot number	number that identifies the lot
expiration date	date after which you cannot use the QC material

Menu Code

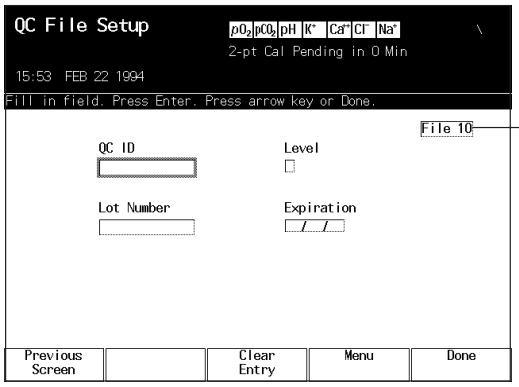
5 1 1

1. Access the QC File screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **1 QC Setup** and press **Enter**.
   c. Select **1 QC Files** and press **Enter**.
2. Select the file number that you want to edit and press **Enter**.

   NOTE: You cannot select File 13 as a QC file.
3. Press **Done**.

   The QC File Setup screen appears as shown in Figure 5-29.

Figure 5-29. QC File Setup Screen for an 850



4. Perform one of the following options.

If you want to . . .	*Then . . .*
change to a new QC lot	type the new QC file information in the fields or, if you use the optional bar code scanner, scan the new QC file information. Continue with step 5.
edit the ranges for this QC file	continue with step 5.
edit fields on this screen	move to the field requiring a change and type the new data. Press **Enter** after you complete each field. Continue with step 5.

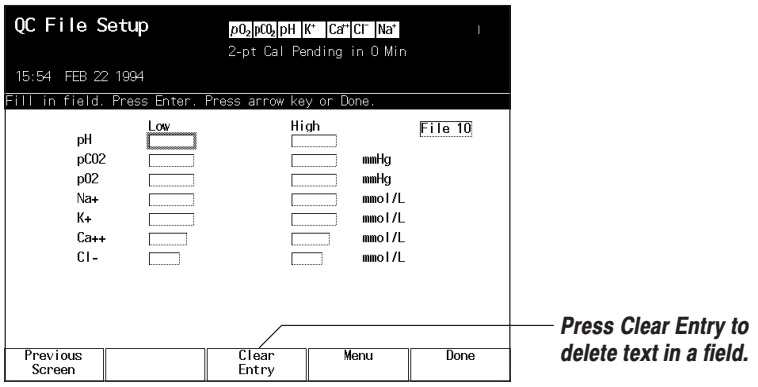
5. Press **Done**.

   A message appears prompting you to delete the current QC file setup data.

   NOTE: You must delete the current QC file data when you change lots. Otherwise, the QC file will contain data from the old and the new lots.

If you are . . .	*Then . . .*
changing to a new QC lot	press **Yes**. The system prints a copy of the current QC file setup data, deletes this data, and prints a copy of the QC statistical summary report. The QC File Setup (ranges) screen appears with all data fields empty, as shown in Figure 5-30. Continue with step 6.
editing the existing QC file ranges	press **No**. The QC File Setup (ranges) screen appears. The fields contain the data for the file you selected. Continue with step 6.

Figure 5-30. QC File Setup (Ranges) Screen for an 850



6. Perform one of the following options.

If you are . . .	*Then . . .*
changing to a new QC lot	type the high and low target limits for each parameter. Press **Enter** after you complete each field. **NOTE:** If you use the optional bar code scanner to enter QC information, scan the QC Parameter bar codes.
editing a portion of the existing QC file ranges	move to the field requiring change, press **Clear Entry** and type the new data. Press **Enter** after you complete each field.
editing all of the existing QC file ranges	press the **Erase All** key to delete the target ranges for all fields. A dialog box appears on the screen asking you to confirm that you want to delete the target ranges in all fields. Press **OK** to clear all fields. Press **Cancel** to keep the target ranges.

7. If a second screen of parameters exists, press **Next Screen**.

8. Press **Done** when you finish.

   A message appears prompting you to set up another QC file.

If you want to . . .	*Then press . . .*
save changes and edit another QC file	**Yes**. The QC File screen reappears. Continue with step 2.
save the entries and you do not want to edit another file	**No**. The Menu screen appears. You can define another setup function or press **Exit Menu** to return to the Ready screen.
return to the QC File Setup (ranges) screen	**Cancel**. The cursor returns to the last field you completed.

Procedural Notes

If you press Menu before you press Done in the QC File Setup screen, a message appears prompting you to save your changes.

If you want to . . .	*Then press . . .*
save the changes	**Yes**. The Menu screen appears.
delete the changes	**No**. The Menu screen appears. No changes are saved.
return to the screen	**Cancel**. The cursor returns to the last field you completed.

If you scan an incorrect bar code, the Unexpected Bar code message box appears. Press **OK** and then scan the correct bar code.

If you press Done before completing all text fields in a row, the Incomplete Data Entry message appears. Press **OK** and complete the required fields.

Selecting Automatic QC File Assignment

Use this procedure to control the way QC results are assigned to a QC file. Table 5-19 describes the options for assigning QC results.

Table 5-19. Auto Identify Options

Option	Description
On	The system automatically determines the appropriate QC file to assign QC sample results, by comparing the QC sample results for pH and pCO_2 to the ranges entered in setup for these parameters. **NOTE:** If the pH, pCO_2, or tHb sensor is disabled or not in calibration, Auto ID does not work.
Off	The operator assigns the QC sample results to the appropriate file. The default value is Off.

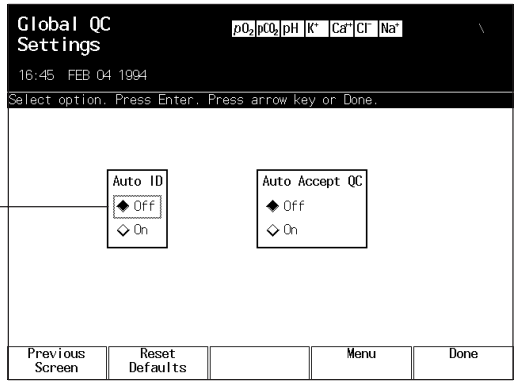
Menu Code

5 ***1*** ***2***

1. Access the Global QC Settings screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **1 QC Setup** and press **Enter**.
   c. Select **2 Global QC Settings** and press **Enter**.

   The Global QC Settings screen appears with the cursor in the Auto ID frame, as shown in Figure 5-31.

Figure 5-31. Global QC Settings Screen



Select On or Off from the Auto ID field and press Enter.

2. Select **On** or **Off** and press **Enter**.
3. Press **Done**.
4. Define another setup function or press **Exit Menu** to return to the Ready screen.

Selecting Automatic Acceptance of QC Results

Use this function if you are connected to an LIS or data management system and you want the 800 system to automatically accept QC results. When you use Auto Accept with Auto Send, the 800 system accepts all QC samples and sends them to the connected LIS or data management system. You can review the QC results at the LIS or data management system and, if required, change the status to reject or discard.

NOTE: Auto Send must be turned on to have results automatically sent to an LIS or data management system.

Table 5-20. Auto Accept QC Options

Option	*Description*
On	The system automatically accepts QC results and, when Auto Send is on, sends the results to an LIS or data management system.
Off	The operator accepts, rejects, or discards QC results at the end of analysis. The default setting is Off.

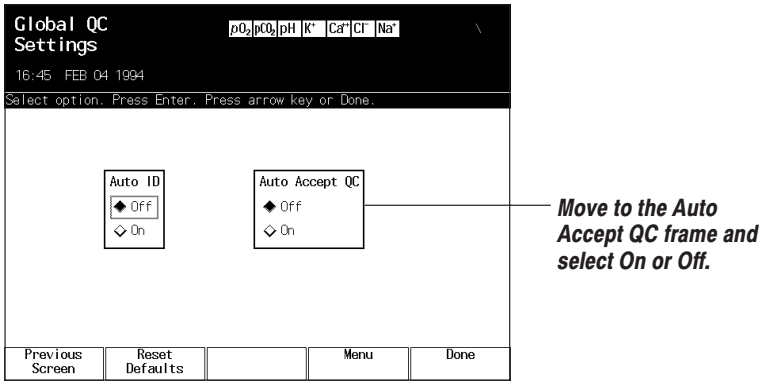
Menu Code

5 ***1*** ***2***

1. Access the Global QC Settings screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **1 QC Setup** and press **Enter**.
   c. Select **2 Global QC Settings** and press **Enter**.

   The Global QC Settings screen appears, as shown in Figure 5-32.

Figure 5-32. Global QC Settings Screen



2. Move to the Auto Accept QC frame.
3. Select **On** or **Off** and press **Enter**.
4. Press **Done**.

5. Define another setup function or press **Exit Menu** to return to the Ready screen.

Selecting Automatic Transmission of QC Results

Use this procedure to control transmission of QC results directly to an LIS or data management system. This option is available only if your 800 system is connected to an LIS or data management system. Refer to *Defining Automatic Transmission of Results*, page 5-38, for the procedure to define patient sample auto send.

Table 5-21. Auto Send QC Results Options

Option	*Description*
On	The system automatically transmits QC results to an LIS or data management system. The default setting is On.
Off	Results are not automatically transmitted. The operator must press **Send** to transmit results or press **Do Not Send** to prevent transmission.

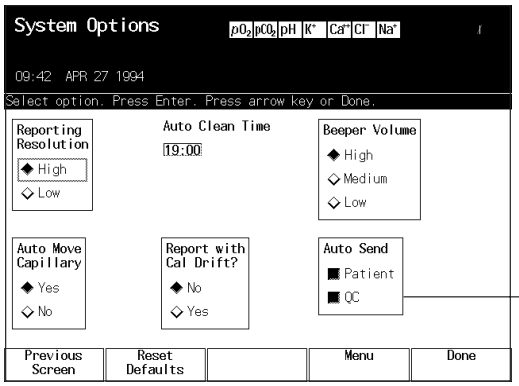
Menu Code

6 ***5***

1. Access the Systems Options screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **5 Systems Options** and press **Enter**.

   The Systems Options screen appears, as shown in Figure 5-33.

Figure 5-33. Systems Options Screen for an 850



2. Move to the Auto Send frame.
3. Select **QC** and press **Enter**. A dark box indicates the option is on.
4. Press **Done**.
5. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Printing a QC Setup Report

Use this procedure to print a QC setup report for any QC file.

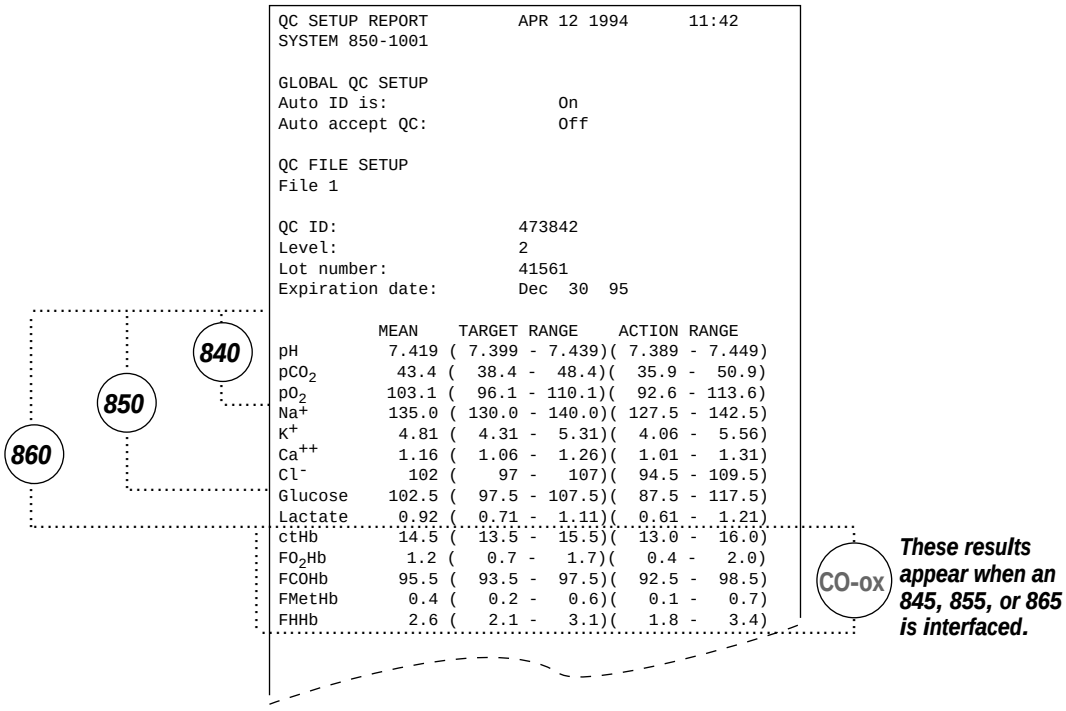
Menu Code

5 1 1

1. Access the QC File screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **1 QC Setup** and press **Enter**.
   c. Select **1 QC Files** and press **Enter**.
2. Select the file number that you want to print.
3. Press **Print QC Setup**.

   The QC Setup report prints. Figure 5-34 shows an example of a QC Setup Report.

Figure 5-34. QC Setup Report



4. Press **Menu**.
5. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Defining Calibration Options

This section describes procedures for the following calibration options:

- changing drift limits
- changing calibration gas values
- selecting calibration frequency and Auto Repeat

Defining Drift Limits

Use this procedure to enter the drift limits allowed during calibrations. Drift is the difference between the value expected from a known calibrant and the actual value measured during the calibration. Some drift is acceptable. This procedure lets you define the acceptable drift limits for your laboratory.

If drift exceeds the acceptable limits, the results are flagged on the screen and on the report and are reported in the status log. The drift limits defined in Table 5-22 are for cal points only. The drift limits for slope points are fixed and cannot be changed. Table 5-22 lists the valid range and default value for each parameter for the listed base models and base models with CO-ox module.

Table 5-22. Valid Entry Ranges for Drift Limits

Parameter	*Valid Range*	*Default Value*	*System*
pH	0.000 – 0.050	±0.015	840, 850, 860
pCO_2	3.5 – 9.0%	±5.6%	840, 850, 860
pO_2	2.0 – 7.0%	±4.1%	840, 850, 860
Na^+	0.00 – 10.00	±2.5	850, 860
K^+	0.00 – 1.00	±0.15	850, 860
Ca^{++}	0.00 – 1.00	±0.05	850, 860
Cl^-	0.0 – 10.0	±3.0	850, 860
Glucose	3.5 – 12.5	±9.0	860
Lactate	0.05 – 0.40	±0.10	860
tHb	0.0 – 0.4	±0.2	base model with a CO-ox module

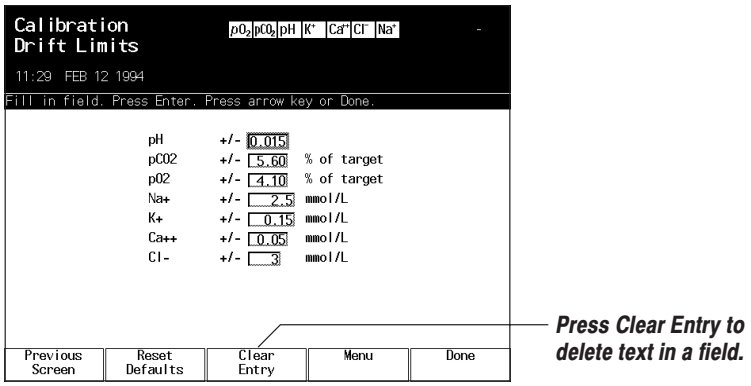
Menu Code

5 6 1

1. Access the Calibration Drift Limits screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **6 Calibration Setup** and press **Enter**.
   c. Select **1 Drift Limits** and press **Enter**.

   The Calibration Drift Limits screen appears, as shown in Figure 5-35.

Figure 5-35. Calibration Drift Limits Screen for an 850



2. Move to the field that you want to change.

   NOTE: The number you enter establishes a range above and below the expected value. For example, if you enter 2 as the drift limit, the range is plus or minus 2 from the expected value.

3. Type the new drift limit and press **Enter**.
4. Repeat steps 2 and 3 for each parameter for which you want to enter or change the drift limit.
5. Press **Done** when you finish.
6. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Procedural Notes

If you type an invalid value in a field and press Done, the Invalid Entry message box appears. Press **OK** and type a valid entry in the field.

Defining Calibration Gas Values

Use this procedure to define the calibration gas values for the gases used during calibration. Table 5-23 lists slope and cal ranges for pCO_2 and pO_2.

Table 5-23. Calibration Gas Values

Gas	Cal Range	Cal Default	Slope Range	Slope Default
pCO_2	2.00 – 7.90%	5.00%	(Cal CO_2 + 2.9) – 99.9%	10.00%
pO_2	5.00 – 98.00%	12.00%	0.00% (fixed)	0.00%

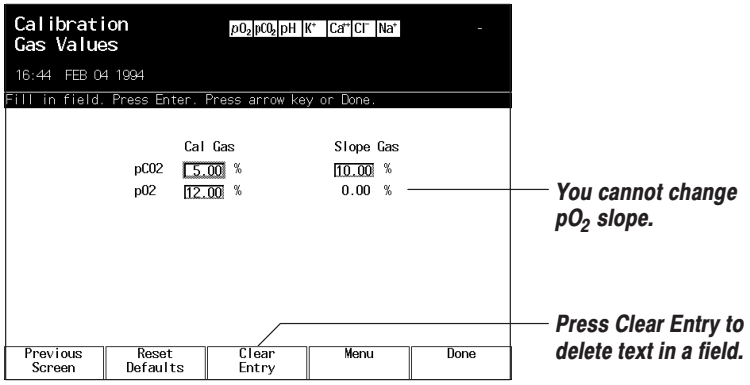
Menu Code

5 6 3

1. Access the Calibration Gas Values screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **6 Calibration Setup** and press **Enter**.
   c. Select **3 Gas Values** and press **Enter**.

   The Calibration Gas Values screen appears, as shown in Figure 5-36.

Figure 5-36. Calibration Gas Values Screen



2. Move the cursor to the field that you want to change.
3. Type the new gas value and press **Enter**.
4. Repeat steps 2 and 3 for each gas value you want to change.
5. Press **Done**.
6. Define another setup function or press **Exit Menu** to return to the Ready screen.

Selecting Calibration Frequency and Automatic Repeat

Use this procedure to select the frequency at which automatic calibrations occur and to direct the system to repeat calibrations automatically whenever the drift is out of limits. There are two calibration frequency options: fixed time and flexible time. Table 5-24 describes the Calibration Frequency and Auto Repeat options.

Table 5-24. Calibration Frequency and Auto Repeat Options

Option	Description
Fixed Time	Lets you schedule one- and two-point calibrations to occur at regular intervals. You enter the time intervals in the One-point Interval and Two-point Interval fields. With Fixed Time, you can also control the Auto Repeat function. One-point intervals range from 05 to 60 minutes; default is 30 minutes. Two-point intervals range from 120 to 240 minutes; default is 120 minutes. The tHb slope interval ranges from 1 to 30 days; default is 30 days.
Flexible Time	The system determines the rate of drift and schedules the time of the next calibration to avoid excessive drift in subsequent calibrations. Flexible Time schedules the one-and two-point calibrations and lets you define a minimum time interval for one-point calibrations. Auto Repeat is always turned on when you select flexible time.
Auto Repeat	This option is available when you select Fixed Time frequency. You can choose to have the system automatically repeat the calibration or a portion of a calibration when the drift is out of limits. The default value is On. In Flexible Time, all calibrations automatically repeat when the drift is out of limits. **NOTE:** The tHb slope does not automatically repeat when the drift is out of limits.
Metabolite Recal	This option allows you to turn off the metabolite recal. Turning off metabolite recal allows faster throughput of samples. When you turn off metabolite recal, the system calibrates glucose only at the regularly scheduled one- and two-point calibrations.

Menu Code

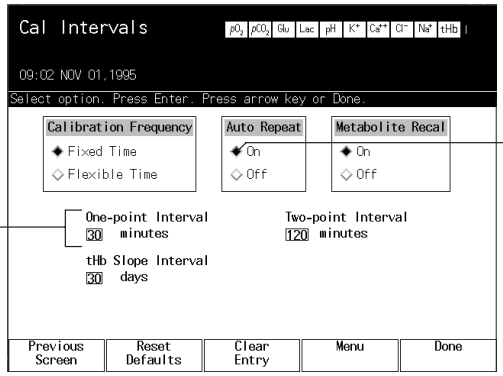
5 ***6*** ***2***

1. Access the Cal Intervals screen from the Menu screen:
   a. Select **5 Operating Setup** and press **Enter**.
   b. Select **6 Calibration Setup** and press **Enter**.

c. Select **2 Cal Intervals** and press **Enter**.

The Cal Intervals screen appears with the cursor in the Calibration Frequency frame, as shown in Figure 5-37.

Figure 5-37. Cal Intervals Screen for an 850



Select On if you want calibrations to repeat automatically.

Both interval fields appear when you select Fixed Time. Only the One-point Interval field appears when you select Flexible Time.

2. Select the options you want.

If you want to change . . .	*Then . . .*
Calibration Frequency	Select Fixed Time or Flexible Time and press **Enter**. **NOTE:** If you select Flexible Time the interval and Auto Repeat options are not available.
One-point, Two-point, or tHb Slope Interval	a. Move to the appropriate field. b. Type the amount of time you want between calibrations and press **Enter**.
Auto Repeat	a. Move to the Auto Repeat frame. b. Select **On** and press **Enter** to automatically repeat calibrations. Select **Off** and press **Enter** to stop repeat automatic calibrations.
Metabolite Recal	a. Move to the Metabolite Recal frame. b. Select **On** and press **Enter** to perform one-point metabolite calibrations automatically. Select **Off** and press **Enter** to stop automatic one-point metabolite calibrations.

3. Press **Done** when you finish.
4. You can define another setup function or press **Exit Menu** to return to the Ready screen.

Configuring for External Devices

Use the following procedures to configure the 800 system for any of the following external devices:

- 270 CO-oximeter
- 800 series compatible ticket printer
- Bayer Diagnostics data management systems
- bar code scanner
- line printer
- laboratory or hospital information system

Table 5-25 lists the ports you can use with each device.

Table 5-25. Ports and Devices

Select . . .	*To connect . . .*
Serial port 1	the ticket printer.
Serial port 2 and 3	the 270 CO-oximeter and an LIS or data management system.
Parallel port	other printer types, such as a line printer.
Barcode	the bar code scanner.

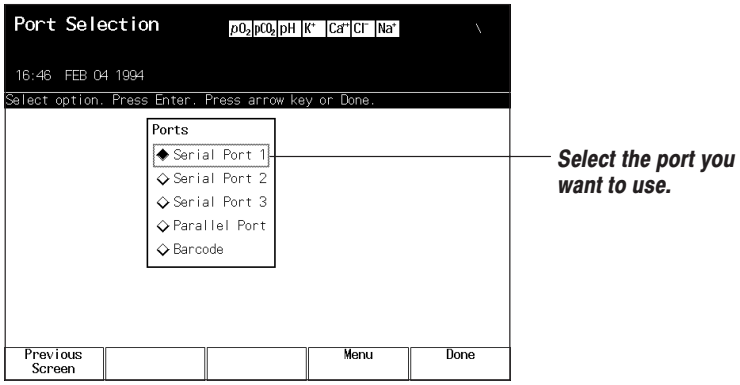
Menu Code

6 6

1. Access the Port Selection screen from the Menu screen:
   a. Select **6 System Setup** and press **Enter**.
   b. Select **6 Communications** and press **Enter**.

   The Port Selection screen appears, as shown in Figure 5-38.

Figure 5-38. Port Selection Screen for an 850



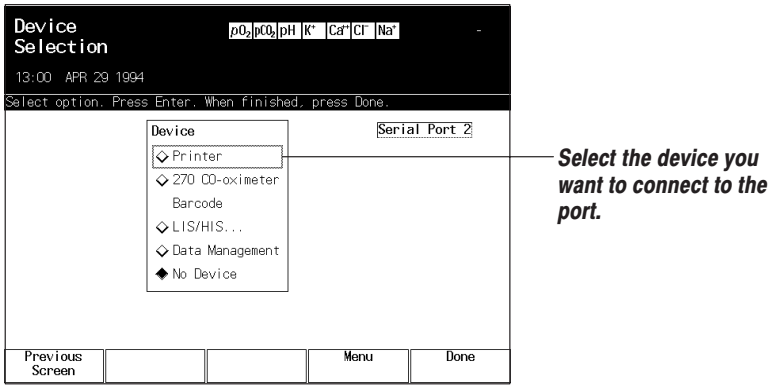
2. Select the appropriate serial port, press **Enter**, and then press **Done**.

   Refer to Table 5-25 to determine which port to select for your device.

   The Device Selection screen appears, as shown in Figure 5-39. If the port already has a device assigned, that device is selected. If required, press **Previous Screen** and select another port.

   NOTE: You can only select a device that has the diamond symbol before it. If a device cannot be connected to the selected port the diamond symbol is absent.

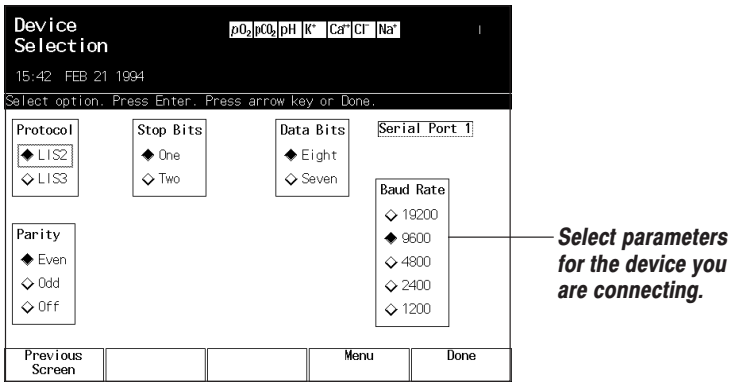
Figure 5-39. Device Selection Screen for an 850



3. Select the required device, and then press **Enter.**

If you . . .	*Then . . .*
select Bar Code	press **Next Screen**. The Bar Code Options screen appears. Select the appropriate symbology. Select **No Additional Symbology** if Code 128 is the only symbology you require. Then press **Enter**. Symbology 128 is always enabled when you install the bar code scanner. You cannot select or deselect it from the menu. You may select one more symbology in addition to code 128. Refer to the *800 Series Bar Coding Features* technical bulletin for detailed information on barcode setup. Press **Done** when you finish.
select LIS/HIS	press **Next Screen**. The Device Selection screen appears containing the communication parameters, as shown in Figure 5-40. Continue to Step 4.
select any other device	press **Done**. You are prompted to configure another port. If you press **No**, the Menu screen appears. If you press **Yes**, the Port Selection screen appears.

Figure 5-40. Device Selection (Communication Parameters) Screen



4. Select the parameters according to the communication requirements for the device you are connecting. Table 5-26 describes each of the communication parameters.

Table 5-26. Communication Parameters

Parameter	*Description*
protocol	the set of conventions that governs the format and timing of the information transferred between the 800 system and the LIS, HIS, or data management system
baud rate	speed at which data is sent or received when devices are communicating through a serial channel
parity	method used to detect errors during transmission by setting an extra binary digit on the basis of the number of 1 bits in a one-byte data item
stop bits	a binary digit that signals that the transmission of a byte of data is complete; used for synchronization
data bits	the number of binary digits that define a unit of information

5. Press **Done** when you finish.

   You are prompted to configure another port.

If you . . .	*Press . . .*
want to configure another device	**Yes**. The Port Selection screen appears.
do not want to configure another device	**No**. The Menu screen appears. You can define another setup function or press **Exit Menu** to return to the Ready screen.
want to return to the last field edited	**Cancel**.

Procedural Notes

When the system establishes the connection to an external device, the Device Connected to Port __ message appears in the status area. If the system is unable to establish the connection, the D60 Port Error message appears.

Refer to the *800 Series Bar Coding Features* technical bulletin for detailed information about bar code setup procedures.

Service Setup Information

Bayer Diagnostics Service Representatives use the Service Setup menus to enter various types of system and service information, such as the system model number, the serial number, and the service contact. You can view the system information, but you cannot change any of the information. Refer to *Viewing System Information* on page 5-5 for the procedure to view the system information.

Managing Data Files

This section provides the following procedures for managing 800 system data files using the disk utilities:

- back up and restore data files
- archive QC data
- view and print archived QC data
- install system software
- copy patient data files to a diskette in a CSV file format

NOTE: When you backup or archive, use DOS-formatted, 3.5-inch diskettes.

Table 5-27 describes the tasks you can perform using the disk utilities functions.

Table 5-27. Disk Utilities Functions

Use this function . . .	*If you want to . . .*
Backup	copy system files from the hard disk to diskettes that you can use to restore files or to copy troubleshooting trace log information for service representatives if required.
Archive	remove QC data from the hard disk and store it on diskettes.
View Archive	view QC data and print QC reports from archived diskettes.
Restore	copy data from backup diskettes to the hard disk.
Install	install or update operating software on the system.
Copy Files	copy patient data files from the hard disk to a diskette in a CSV file format

You can access disk utilities screens from the Menu screen.

Archiving QC Data

Use this procedure to copy the previous month's QC files and statistics from the hard disk to a diskette. The system copies all QC files at the same time.

You can archive the previous month's QC data one or more times during the current month. At the end of the current month, the system permanently deletes the previous month's QC data.

Use the archive diskette to view and print QC file reports, Levey-Jennings charts, and statistical summary reports of archived QC data. Refer to *Viewing Archived QC Data*, page 5-70, for more information on viewing and printing archived data. You cannot edit or restore data from an archive diskette.

Menu Code

7 ***2*** ***2***

1. Access the Archive QC screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **2 Disk Utilities** and press **Enter**.
   c. Select **2 Archive** and press **Enter**.

   NOTE: If you archive before you analyze the first QC sample of the current month, you can print statistical summary reports of the previous month's QC data before you archive.

2. Perform one of the following options.

If you want to . . .	*Press . . .*
print a QC statistical summary report before archiving	**Print**. The system prints the QC Statistical Summary. When printing is complete, the Begin Archiving message appears, prompting you to insert a diskette.
archive QC data without printing a report	**Archive**. The Begin Archiving message appears, prompting you to insert a diskette.
stop the archiving process	**Cancel**. The system returns to the Archive QC screen. Press **Cancel** again.

3. Insert a DOS-formatted diskette in the diskette drive and press **Continue**.

   The Writing to the diskette message appears during the archive. When archiving is complete, a message box appears containing archive diskette information.

4. Remove the diskette and label it with the date and time of archive.
5. Press **OK**.
6. Press **Home** to return to the Ready screen.

Procedural Notes

If you do not insert a diskette, the No Diskette in Diskette Drive message box appears. If you insert an unformatted diskette, the Cannot Write to Diskette message box appears.

If . . .	*Then . . .*
you want to continue to archive	insert a formatted diskette and press **Continue**.
you do not want to continue to archive	press **Cancel**. The Cancel Archive screen appears. Press **Yes**. The Menu screen appears.

If you insert a diskette that already contains data, a message box appears indicating that the system will overwrite the data currently on the diskette.

If . . .	*Press . . .*
you want to overwrite the data	**Continue**. The system starts archiving the data.
you do not want to overwrite the data	**Cancel**. The Begin Archiving message appears. Press **Cancel** again.

If you press **Cancel** at the Begin Archiving message, you are prompted to cancel archiving.

If . . .	*Press . . .*
you want to continue to archive	**No**.
you do not want to continue to archive	**Yes**. A message appears prompting you to remove the diskette.

Viewing Archived QC Data

Use this procedure to view QC data from archive diskettes. You can also print the following QC reports from archive diskettes:

- Levey-Jennings Chart
- QC Sample Report
- QC Statistical Summary

NOTE: You cannot edit or restore archived QC data.

Menu Code

7 ***2*** ***3***

1. Access the View Archived QC Data screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **2 Disk Utilities** and press **Enter**.
   c. Select **3 View Archive** and press **Enter**.

   The View Archived QC Data screen appears, with the Begin Viewing Archive message box.
2. Insert the archived diskette in the diskette drive and press **Continue**.

   The system reads the diskette. When the system is ready, a message appears containing archive diskette information.
3. Press **Continue**.
4. Remove the diskette when the system prompts you. The Archived QC Search Criteria screen appears.
5. Type the search criteria and press **Enter** after you complete each field. Refer to *Recalling QC Data* in Section 2, for information about entering the search criteria.
6. Press **Done** when you finish entering your search parameters.

If . . .	***Then . . .***
more than one QC sample is found	the Archived QC Search Log appears. The log contains the reports that the system located for the search criteria you entered. Continue with step 7.
one QC sample is found	the Archived QC Search Result screen appears. Continue with step 8.

7. Perform one of the following tasks.

If you want to . . .	*Then . . .*
view the report results	select the QC sample you want and press **Enter**.
print a Levey-Jennings, QC sample, or statistical summary report	press **Reporting Options**. Continue with step 9.

8. Press **Reporting Options** to print a Levey-Jennings, QC sample, or statistical summary report.
9. Select the report you want to print.

If you want to print a . . .	*Then . . .*
Levey-Jennings Chart	a. Select Levey-Jennings Current Month or Previous Month. b. Press **OK**. The list of parameters appears. c. Select the parameter you want and press **Done**. The Levey-Jennings chart appears.
QC Sample Report	a. Select Print QC Sample Report and press **Enter**. b. Press **OK**.
QC Statistical Summary	a. Select Print Statistical Summary and press **Enter**. b. Press **OK**.

10. When you finish viewing archived QC data, press **Done**.

If . . .	*Then . . .*
more than one sample is found	the Done Options message box appears. • Select Next Record and press **OK** to view the next report that appears on the log. • Select Previous Record and press **OK** to view the previous report that appears on the log. • Select Search Criteria Screen and press **OK** to view the Archived QC Search Criteria screen. • Press **Cancel** to close this message box and return to the Search Results screen.
one sample is found	the Archived QC Search Criteria screen appears.

11. Press **Home** to return to the Ready screen.

Procedural Notes

If you type invalid data in a field and press **Done** the system displays either the Invalid Entry or Invalid Range message box. Press **OK** and type a valid entry in the field.

If there is no QC data found for the search criteria you entered, the No QC Data message box appears. Press **OK** and ensure that the search criteria you entered is accurate.

Backing Up System Data

Use this procedure to copy system data files from the hard disk to diskettes. You can also use this procedure to copy trace log information for service representatives to use in troubleshooting software problems.

Backup protects the system files on your hard disk by making copies of the files on a diskette that you can restore to the hard disk. The stored data from the disk includes:

- patient sample data
- quality control data
- calibration, diagnostic, and maintenance data
- setup data
- workload statistics and cycle counts

Establish a backup schedule that meets your laboratory's data requirements. The frequency with which you backup data files should correspond to the amount of data you want to restore in case of a data loss. For example, if you want to be able to restore all your patient sample data from the previous day, then backup patient data every day. Bayer Diagnostics recommends that you backup patient data every day.

NOTE: Bayer Diagnostics recommends that you backup system data files each time you change system setup options and QC files.

You can restore backed up data to the hard disk using the procedure in *Restoring System Data*, in this section.

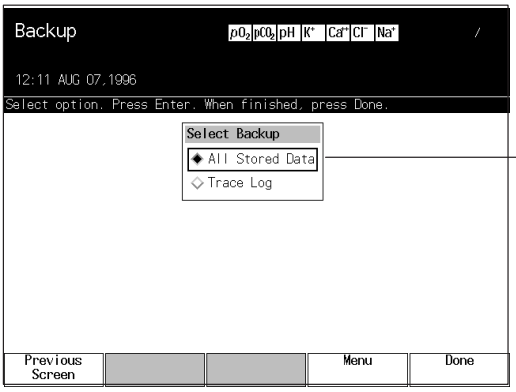
Menu Code

7 2 1

1. Access the Backup screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **2 Disk Utilities** and press **Enter**.
   c. Select **1 Backup** and press **Enter**.

   The Backup screen appears, as shown in Figure 5-41.

Figure 5-41. Backup Screen



All stored data includes patient and QC data, calibrations, diagnostics, workload statistics, and setup.

2. Perform one of the following tasks.

If you want to . . .	*Then . . .*
back up the system data	select **All Stored Data**.
copy the trace log	select **Trace Log**.

3. Press **Done**. The Backing Up message box appears prompting you to insert a diskette.
4. Insert an IBM-formatted diskette in the diskette drive and press **Continue**.

   The Writing to diskette message box appears while the system performs the backup.
5. Complete the backing up process.

If . . .	*Then . . .*
a message appears prompting you to insert a new diskette	a. Remove the diskette from the diskette drive. b. Label the diskette with the date and time. c. Insert another formatted diskette and press **Continue**.
the Backup Finished screen appears	a. Remove the diskette from the diskette drive. b. Label the diskette with the date and time. c. Press **OK**. The Menu screen appears.

6. Press **Home** to return to the Ready screen.

Procedural Notes

If you do not insert a diskette, the No Diskette in Diskette Drive message box appears. If you insert an unformatted diskette, the Cannot Write to Diskette message box appears.

If . . .	*Then . . .*
you want to continue with the backup	insert a formatted diskette and press **Continue**.
you do not want to continue with the backup	press **Cancel**. The Cancel Backup screen appears.

If you insert a diskette that already contains data, a message box appears indicating that the system will overwrite the data currently on the diskette.

If . . .	*Press . . .*
you want to overwrite the data	**Continue**. The system starts backing up the data.
you do not want to overwrite the data	**Cancel**. The Backing Up message box appears. Insert a formatted diskette and press **Continue**.

Restoring System Data

Use this procedure to copy data from your backup diskettes to the system hard disk.

CAUTION: When you restore data from a backup diskette, the restore process replaces any files created since the last back up.

Menu Code

7 2 4

1. Access the Restore screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **2 Disk Utilities** and press **Enter**.
   c. Select **4 Restore** and press **Enter**.

   The Restore screen appears with the Insert Backup Diskette message box.
2. Insert the backup diskette in the diskette drive and press **Continue**.

   The system reads the diskette. When the system is ready, a message box appears containing backup diskette information. The message also indicates that the restore process will overwrite the data currently on the hard disk.
3. Press **Continue**.

   The Restoring screen appears with the Reading from Diskette message box.

4. Complete the restore process.

If . . .	*Then . . .*
a message appears prompting you to insert the next diskette	a. Remove the diskette from the diskette drive. b. Insert another backup diskette and press **Continue**.
the Restore Finished screen appears	Continue with step 5.

5. Press **OK** and the remove the diskette.

   The system performs an automatic shutdown.

   The Shutdown screen appears.

6. Press **Yes** to shut down the system.

CAUTION: You must wait for at least 1 minute before you disconnect the power cord and then wait at least 10 seconds before you reconnect the power cord. If you do not adhere to the time intervals, you can damage the system.

A message appears on the screen and on the roll printer, directing you to wait before you disconnect the power.

7. Wait at least 1 minute.
8. Disconnect the power cord from the power supply.
9. Restart the system:
   a. Wait at least 10 seconds after disconnecting the power cord.
   b. Reconnect the power cord to the power source.

   After a few moments, the system starts initializing. When initializing is complete, a screen for Analyze Mode appears.

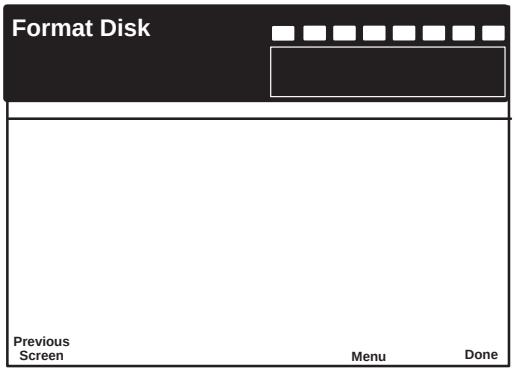
Procedural Notes

Ensure that you restore data to the system hard disk only from the backup diskettes that are labeled for that system.

If you insert a diskette that is not a backup diskette, the Invalid Diskette Data type message appears.

If . . .	*Then . . .*
you want to continue	insert the correct diskette and press **Continue**.
you do not want to continue	Press **Cancel.** The Cancel Restore message appears.

If you want to cancel the restore process, press **Cancel**. When prompted, press **Yes** and remove the diskette from the diskette drive.



Installing Software

Use this procedure to install or update operating software on your 800 system. You update system files using program diskettes that contain new system software.

CAUTION: To protect against data loss, always back up files before installing new software. Refer to the procedure, *Backing Up System Data*, page 5-72.

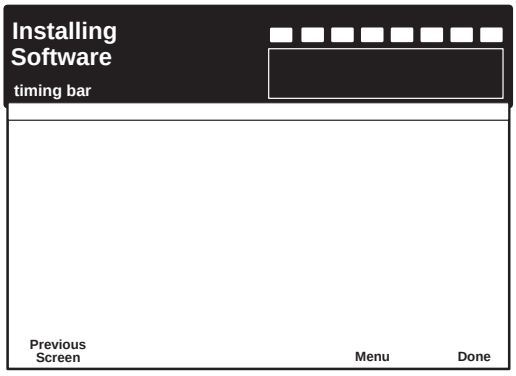
Menu Code

7 ***2*** ***5***

1. Access the Install Software screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **2 Disk Utilities** and press **Enter**.
   c. Select **5 Install** and press **Enter**.

   The Install Software screen appears with a message prompting you to back up the system before installing software.
2. Press **Continue** if you have backed up the system.

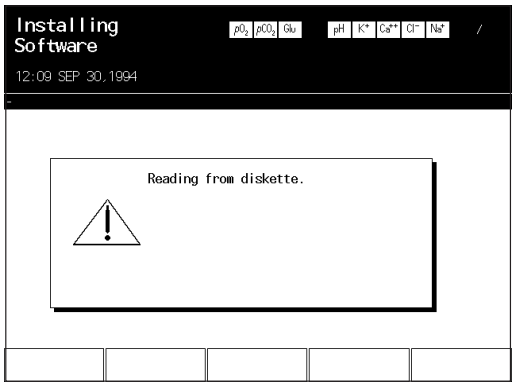
   A message appears prompting you to insert the program diskette.



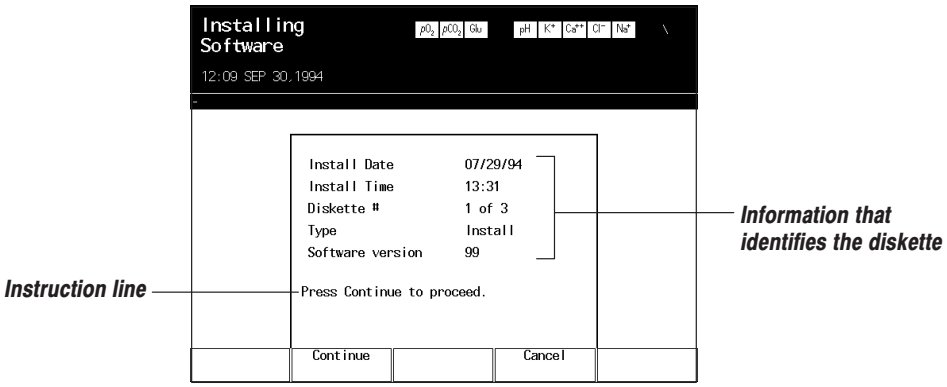
3. Insert program diskette one.

4. Press **Continue** to proceed.

   The following message appears:



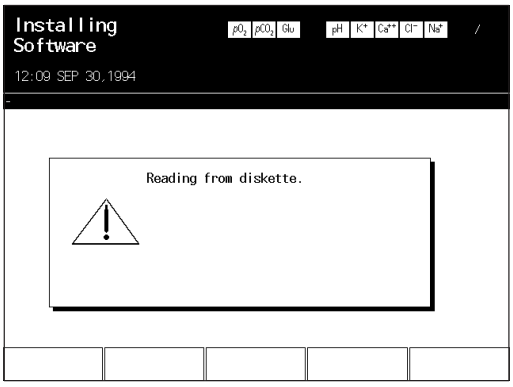
   The system identifies the diskette and displays the Install Identification message box:



CAUTION: Do not remove the diskette.

5. Press **Continue** to proceed using the diskette the system just read.

   The system copies the software files from the diskette to the hard disk:



6. After the system copies the software files, the Install Identification message box appears.

If . . .	*Then . . .*
you have more program diskettes to install	the Insert Next Diskette message appears on the Install Identification message box instruction line. **NOTE:** Do not press Continue until you have inserted the diskette. a. Remove the diskette from the diskette drive. b. Insert the next program diskette. c. Repeat steps 4 and 5.
the Last Diskette message appears on the Install Identification message box instruction line	a. Press **OK**. A message appears prompting you to remove the diskette. b. Remove the diskette from the diskette drive. The Processing Software Installation message appears. The system emits a beep every few seconds until the installation is complete.

NOTE: If the Last Diskette message does not appear after the system reads the last program diskette, it is likely that at least one of the program diskettes was not installed. Cancel the installation and start the procedure again.

When the system finishes the software installation, the Install Software Finished screen appears prompting you to shut down the system.

7. Press **OK** to shut down the system.

   The system initiates an automatic shut down.

   A message appears on the screen and on the roll printer, directing you to wait before you disconnect the power.

CAUTION: Do not unplug the system until the following message appears on the screen:

```
...synching disks... done
```

This is an operating system message, indicating that the system has successfully completed the shutdown procedures. Unplugging the system before this message appears can damage the system.

8. When you see the operating system message, disconnect the power cord from the power supply.

CAUTION: Wait at least 10 seconds before you reconnect the power cord. If you do not adhere to the time intervals, you can damage the system.

9. Restart the system:
   a. Wait at least 10 seconds after disconnecting the power cord.
   b. Reconnect the power cord into the power source.

   The system restarts. After a few moments, the system starts initializing. When initializing is complete, a screen for Analyze Mode appears.

   The software version number appears on the System Information screen with the date and time of installation.

Procedural Notes

If you insert a diskette that has already been processed, a message box appears prompting you to insert a different diskette.

If the system encounters a diskette containing an invalid data type or a diskette that it cannot read, a message appears prompting you to remove the diskette and insert another one.

If you want to cancel the software installation, press **Cancel**. When prompted, press **Yes** and remove the diskette from the diskette drive. If you cancel the installation, the previous version of the software remains installed.

CAUTION: Occasionally the system may shut down if you cancel the installation. If this happens, follow the instructions given in the Caution statement in step 7 and then continue through step 9.

When the screen for the Analyze Mode appears, you can start the installation procedure again.

Copying Files

Use this procedure to copy patient data files from the hard disk on your 800 system to a diskette. The system copies the data to the diskette in a CSV file format. You can then import this data into PC applications, such as spreadsheets and databases, that accept comma-delimited lists of ASCII-text information. You can use these applications for data analysis or management. Refer to *File Format*, page 5-81, for more information about how the data is stored in the copied files.

Menu Code

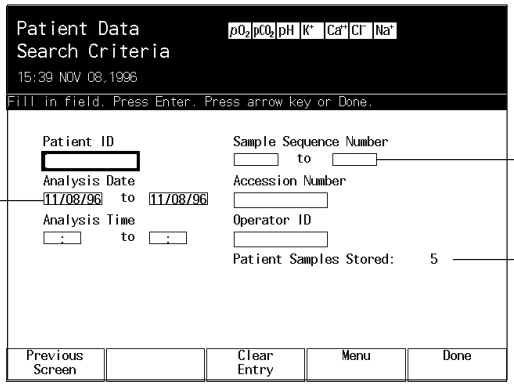
7 *2* *6*

1. Access the Copy Files screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **2 Disk Utilities** and press **Enter**.
   c. Select **6 Copy Files** and press **Enter**.

   The Copy Files screen appears.
2. Select Patient Data and press **Done**.

   The Patient Data Search Criteria screen appears, as shown in Figure 5-42.

Figure 5-42. Patient Data Search Criteria Screen



Enter a range of dates for the files you want to copy.

Enter a series of sample sequence numbers for the files you want to copy.

This field displays the number of samples stored in system.

Use this screen to define the criteria for the patient data files you want to copy. The system locates only the files that meet the criteria you specify. For example, if you want to copy patient data files from a specific period, type in the start date in the Analysis Date From field and the end date in the Analysis Date To field. You can also copy files with consecutive sample sequence numbers.

NOTE: The system can copy up to 1500 patient samples on a single diskette. If your search criteria produce too many samples to fit on a single diskette, the system prompts you to reenter the search criteria to select fewer samples.

3. Type the search criteria and press **Enter** after you complete each field. Press **Done** when you finish.

   The Copying Files screen appears, with the Begin Copying Files dialog box.

4. Insert a clean, formatted diskette in the diskette drive and press **Continue**.

   The Writing to diskette message box appears while the system copies the files.

5. When the Copy Files Finished screen appears, remove the diskette and label it.

Procedural Notes

If you do not insert a diskette, the No Diskette in Diskette Drive message box appears. If you insert an unformatted or faulty diskette or a diskette that already contains files, the Cannot Write to Diskette message box appears.

If . . .	*Then . . .*
you want to copy files	insert a clean, formatted diskette and press **Continue**.
you do not want to copy files	press **Cancel**. The Copying Files screen appears, with the Cancel Copy Files dialog box.

File Format

The Copy Files option allows you to copy patient data files stored on your system to a diskette in a format that can be imported into PC applications, such as spreadsheets and databases. You can then use these applications for data management and analysis.

The copied data files are in a CSV format, which uses a comma-delimited record structure. The files contain ASCII characters without character formatting. For example, pCO_2 appears as pCO2.

The numbers in the sample status and parameter status columns represent messages, such as out-of-range messages, in the original patient sample report. Refer to the Sample Status and Parameter Status tables that appear in the patient data file for an explanation of the status number.

When imported into a PC spreadsheet, the data in each file is organized in rows:

Row	Contents
1	The first row contains headings that define the contents of the column. These headings list patient demographics or parameter names as found on an 800 system. The copied file includes all headings, even if there are no patient results in the columns.
2	The second row contains the status heading and the units of measure for each parameter. A status number appears for every parameter with a reported result. Sample status numbers are reported in a separate column.
3 through the end of the file	The remaining rows contain the status numbers, demographic information, and reported values for each patient sample. Each row contains results for a single sample analysis. Columns that are not relevant to the system model or whose values are unavailable are left blank.

The following tables list the status numbers and the associated messages that are reported for sample and parameter status. Although the original patient result may contain more than one message, the copied report lists only one status number. The status numbers are listed in the table in the hierarchical order in which they are reported.

Sample Status Numbers

Status number	Message
Blank	No exceptions
1	Blood gas and CO-ox sample temp out of range
2	Blood gas sample temp out of range
3	CO-ox sample temp out of range
4	Bubbles detected in blood gas and CO-ox sample
5	Bubbles detected in blood gas sample
6	Bubbles detected in CO-ox sample

Parameter Status Numbers

Status number	Message
Blank	No exceptions
1	Entered value
2	Sensor has a drift D2 error
3	Interference detected
4	If blood, question data
5	>1.5% SulfHb detected
6	Above reference range
7	Above action range
8	Below reference range
9	Below action range

Standby and Shutdown

This section describes procedures to place the 800 system in standby and to shut down the system.

Standby is an inactive state that disables the automatic calibration functions to reduce reagent consumption. During Standby, the system continues to perform purge sequences to maintain the integrity of the sensors, and it performs the Auto Clean sequence.

Shutdown discontinues all operations in an orderly fashion. Always perform a shutdown procedure before you disconnect the power cord to perform maintenance or troubleshooting procedures.

Placing the System in Standby

Place the system in standby when sample analysis is not required for a prolonged period of time. Using standby reduces reagent consumption by turning off automatic calibrations. While in standby, the system performs the scheduled auto clean and purges the sensors on a regular basis.

Menu Code

7 ***1***

1. Access the Set Standby screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **1 Standby** and press **Enter**.
2. Place the system in standby.

If you want to . . .	*Then . . .*
schedule a date and time to exit standby	Type the date and time. a. Type the month, date, and year in the selected format and press **Enter**. b. Type the hour and minutes in the format HH:MM. Enter 0 – 23 hours and 0 – 59 minutes. c. Press **Done** to enter standby.
place the system in standby indefinitely	Press **Done**.

The Standby screen appears. If you do not type the date and time to exit standby, the Date and Time fields do not appear.

The system remains in standby until the scheduled date and time or until you exit standby manually.

3. Exit standby.

If you want to exit standby . . .	*Then . . .*
automatically	Do nothing. The system automatically exits standby at the scheduled date and time.
manually	Press **Exit Standby** or **Home**.

After the system exits standby, it performs the required calibrations and returns to the Ready screen.

Procedural Notes

If you turn off the power while the system is in standby, the system returns to standby when you turn on the power.

If the system is scheduled to perform an automatic calibration while in standby, the calibration starts when the system exits standby. If multiple calibrations are pending, the system performs a two-point calibration.

Shutting Down and Restarting the System

Use this procedure to shut down the system before you perform service and to restart the system when finished.

Menu Code

7 3

1. Access the Shutdown screen from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **3 Shutdown** and press **Enter**.
2. Press **Yes**.

   A message appears on the screen and on the roll printer, prompting you to wait before you disconnect the power.

⚠ **CAUTION:** Do not unplug the system until the following message appears on the screen:

```
...synching disks... done
```

This operating system message indicates that the system has successfully completed the shutdown procedures. Unplugging the system before this message appears can damage the system.

3. When you see this message, disconnect the power cord from the power supply.

⚠ **CAUTION:** Adhere to the time interval or damage can occur to the system.

4. Wait at least 10 seconds after disconnecting the power cord, then reconnect the power cord into the power source.

   After a few moments, the system starts initializing. When initializing is complete, a screen for Analyze Mode appears.

Procedural Notes

In the event of a power failure or a power surge and the system shut down, perform a two-point calibration when the system completes initializing.

Appendixes

Appendix A: Protecting Yourself from Biohazards

This appendix summarizes the established guidelines for handling laboratory biohazards. The summary is based on the guidelines developed by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and Guideline M–29A from the National Committee for Clinical Laboratory Standards (NCCLS): *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood and Tissue, Approved Guideline*.[7,8]

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents that are biological in nature, such as the hepatitis B virus (HBV), the human immunodeficiency virus (HIV), or the tubercle bacillus. These infectious agents may be present in human blood and blood products or in other body fluids.

The major sources of contamination when handling potentially infectious agents are as follows:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact
- direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves when touching the screen, which can be contaminated by contact with body fluids from gloves or splattering.
- Wear gloves while servicing parts of the instrument that have contact with body fluid such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation are possible.
- Wear protective clothing such as lab coats or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.

- Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the instrument sample path or waste area with 15% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

To prevent needlestick injuries, needles should not be recapped, purposely bent, cut, broken, removed from disposable syringes, or otherwise manipulated by hand.

Appendix B: Obtaining Service and Supplies

This appendix provides the following service and supply information:

- addresses and communication numbers for obtaining service and technical information and for ordering supplies and accessories
- system warranty and service delivery policy information
- a list of the system supplies that you are most likely to order

Addresses and Communication Numbers

For technical assistance contact your local authorized representative.

For customer service or additional information contact your local authorized distributor.

Bayer Argentina S.A.
División Diagnósticos
Ricardo Gutiérrez 3652
B1605EHD Munro – Buenos Aires
Argentina
54 11 4 762 7000

Bayer Australia Limited
Diagnostics Business Group
2 Keith Campbell Court
Scoresby
Victoria 3179 Australia
1 800 034 477

Bayer Austria GesmbH
Geschäftsbereich Diagnostika
Lerchenfelder Gürtel 9–11
A–1164 Wien,
Austria
43 – 1– 71146 – 2411

Bayer s.a.–n.v.
Division Diagnostics
Avenue Louise 143 Louizalaan
1050 Bruxelles–Brussel,
Belgium 32 2 535 66 81

Bayer S.A.
Produtos Diagnósticos
Rua Domingos Jorge 1100
04779–900 – São Paulo – SP
Brazil
55 11 5694 5574

Bayer Inc.
Bayer Diagnostics
Healthcare Division
77 Belfield Road
Toronto, OntarioCanada M9W 1G6
416 248–0771

Bayer S.A.
División Diagnóstica
A.A. 80387
Av. de las Américas No 57–52
Santafé de Bogotá, D.C. – Colombia
(571) 4234199–4234352

Bayer A/S
Nørgaardsvej 32
DK–2800 Lyngby,
Denmark
+ 45 45 23 50 00

(Continued)

Bayer OY
Suomalaistentie 7
FIN 02270 Espoo,
Finland
+ 35 89 88 78 87

Bayer Diagnostics
Tour Horizon
52, quai de Dion Bouton
92807 Puteaux Cedex, France
01 49 06 56 00

Bayer Vital GmbH & Co. KG
Geschäftsbereich Diagnostics
Siemensstraße
3D–35463 Fernwald,
Germany
0049–(0)641–4003–0

Bayer Hellas S.A.
Akakion 54A
Marousi
Athens 151 25, Greece
01 –68 83 648

Bayer Diagnostics Limited
20/F Gee Chang Hong Centre
65 Wong Chuk Hang Road
Hong Kong
852–28147337

Bayer Diagnostics India Limited
589, Sayajipura
Ajwa Road, Baroda – 390019
Gujarat, India
91 265 46 2720

Bayer S.p.A.
Divisione Diagnostici
Via Grosio 10/4
20151 Milano, Italia
+39/023978.1

Bayer Medical Ltd.
Unosawa Tokyu Building 3
F1–19–15, Ebisu
Shibuya–Ku
Tokyo 150–0013, Japan 81.3.3440.4881

Bayer Diagnostics Korea Limited
4/F Kyemyung Building
48–7 Myungil–Dong
Kangdong–Ku
Seoul, Korea 134–07082–2–428–5980

Bayer de México, S.A. de C.V.
Division Diagnósticos
Ave. Colonia del Valle No. 615
Col. del Valle
Delegación Benito Juárez
México, D.F. C.P. 03100 525 7283301

Bayer B.V.
Division Diagnostics
Energieweg 1
3641 RT Mijdrecht, The Netherlands
+31 (0)297 280 666

Bayer As
Brennaveien 18
N–1483 Skytta,
Norway
+ 47 67 06 86 00

Bayer Sp. z o.o.
Al. Jerozolimskie 158
02–326 Warszawa,
Polska
+48(0)225723500

Bayer Portugal S.A.
Divisao PH / DS
Rua da Quinta do Pinheiro, 5
2795–653 Carnaxide, Portugal
351.21.416.50.22

(Continued)

Bayer Puerto Rico Inc.
Diagnostics Division
Victoria Industrial Park
Building #1
Carolina, Puerto Rico
787 752–8989

Bayer (Pty) Ltd.
Healthcare Division
27 Wrench Road
Isando 1600,
South Africa
27 11 921–5048

Química Farmacéutica Bayer, S.A.
División Diagnósticos
Calabria, 268
08029 Barcelona, España
+ 34 93 495.65.00

Bayer AB
Drakegatan 1
S–402 24 Göteborg,
Sweden
+ 46 31 83 98 00

Bayer (Schweiz) AG
Geschäftsbereich Diagnostika
Grubenstrasse 6
8045 Zuerich, Switzerland
0041/1/465 81 11

Bayer Taiwan Company Limited
Diagnostics Division
8/F No. 109 Sec. 2
Keelung Road
Taipei, Taiwan R.O.C.
886–2–23777520

Bayer plc
Diagnostics Division
Bayer House, Strawberry Hill
Newbury, RG14 1JA
United Kingdom
+44 (0)1635 563000

Bayer Corporation
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591–5097 USA
914 631–8000

Bayer Corporation
Diagnostics Division
333 Coney Street
East Walpole, MA 02032–1597 USA
508 668–5000

Standard System Warranty and Service Delivery Policy

Bayer Diagnostics and its authorized distributors provide customers who acquire new Bayer Diagnostics systems with a one-year comprehensive, but limited, warranty. This limited warranty is designed to protect customers from the cost associated with repairing systems that exhibit malfunctions due to defects in materials and/or workmanship during the warranty period.

Warranty Period

The warranty period commences upon installation at the customer's location and extends for a period of one year thereafter. The customer, with some exceptions, may purchase additional service coverage beyond the one year warranty period as part of the original system acquisition for second or subsequent years beyond the original installation date. The customer's original Purchase Invoice or appropriate Agreement Addendum must indicate the term in months for additional service coverage.

Warranty Service During Normal Hours

The customer may obtain warranty service for systems during normal business hours by contacting the Bayer Diagnostics location or authorized distributor. Refer to the list of Bayer Diagnostics locations in this section.

Extent of a Warranty Service Call

During the warranty period, Bayer Diagnostics or an authorized distributor will repair the system during normal business hours, at their expense, subject to the exclusions listed below. Bayer Diagnostics or an authorized distributor will initiate a warranty field service call when notified. The call will be considered complete when the system is again operating to its published specifications and the customer, or the customer's representative, has agreed by signing the appropriate Field Service Report. When service is complete, the customer will receive a copy of the Field Service Report detailing all work performed by the Bayer Diagnostics representative.

Warranty Service Outside Normal Hours

Customers, with some exceptions, may also request warranty service to be delivered outside of normal business hours, including evenings, weekend days, or nationally observed holidays by contacting the Bayer Diagnostics location or authorized distributor. Warranty service performed at these times is subject to a surcharge unless the customer has purchased a service product option that provides warranty service outside normal hours.

Replacement of Parts

In performing warranty service under this agreement, Bayer Diagnostics or its authorized distributors will provide appropriate parts to repair the system at no charge with the exception of certain parts or subassemblies that are considered Customer Maintenance Items. Customer Maintenance Items include, but are not limited to, the following items: lamps, electrodes or sensors (which are covered by a separate warranty), Bayer Diagnostics reagents and calibrators, controls, paper, and pens. Consult the appropriate operator's manual for a complete list of maintenance items for any specific model of system.

Design Changes and Retrofitting of Systems

During the warranty period, Bayer Diagnostics reserves the right to change the design or construction of specific models of systems without incurring any obligation to make such changes available to an individual system. If Bayer Diagnostics notifies customers of a change that improves the performance or reliability of their system, and requests to retrofit that system, customers must agree to allow Bayer Diagnostics or an authorized distributor, at Bayer Diagnostics expense, to retrofit components or make design changes, which will not adversely affect the system's performance characteristics.

Key Operator Designation

Customers will designate a key operator who will be available to Bayer Diagnostics representatives to describe system malfunctions by telephone and/or to perform simple adjustments and corrections as requested. If a key operator is not designated or is unavailable when the customer requests service, the delivery of warranty service may be delayed.

OSHA Requirements (US only)

When service is required at a customer location, the customer must provide the Bayer Diagnostics representative with adequate facilities that comply with the regulations of the Secretary of Labor under the Occupational Safety and Health Act (OSHA) of 1970, as amended.

Warranty Exclusions

Bayer Diagnostics or its authorized distributors will provide warranty service to customers during the warranty period, which includes appropriate parts, travel to the location of the system, and on-site labor during normal business hours. In addition, Bayer Diagnostics or its authorized distributors will provide warranty service during the warranty period only, and system repairs, labor, or replacement parts, as provided during the original warranty period, will not extend the original warranty period.

This warranty will not apply if any of the following occurs:

1. Repairs or modifications have been made to the system by other than an authorized Bayer Diagnostics representative.
2. The system has been operated using other than Bayer Diagnostics brand accessories, or consumable supplies and/or reagents not having the same grade, quality, and composition as defined by Bayer Diagnostics.
3. The system has not been installed within 90 days of shipment to the customer's facility unless otherwise specified.
4. The customer has not performed appropriate customer maintenance procedures, as outlined in the system operator's manual.
5. The system has been misused or used for a purpose for which it was not intended.
6. The system has been damaged in transit to the customer or damaged by the customer while moving or relocating it without supervision by a Bayer Diagnostics representative.
7. Damage was caused by floods, earthquakes, tornados, hurricanes or other natural or man-made disasters.
8. Damage was caused by Acts of War, vandalism, sabotage, arson, or civil commotion.
9. Damage was caused by electrical surges or voltages exceeding the tolerances outlined in the system operator's manual.
10. Damage was caused by water from any source external to the system.
11. The customer has purchased an alternative agreement whose terms of warranty supersede this agreement.

Bayer Diagnostics or its authorized distributors will invoice customers, at current standard labor and parts rates, for systems repaired to correct damage or malfunctions due to any of the reasons listed above.

Limitations of Bayer Diagnostics Original Warranty

Bayer Diagnostics warrants to all customers that service will be performed in a professional manner consistent with the industry. If the system is not performing according to its specifications, Bayer Diagnostics will, at its option, repair or replace the system. This is the customer's sole and exclusive remedy for breach of warranty.

Other than as stated above, there are no other warranties, express or implied, accompanying either the leasing of the equipment or its sale to the customer at the expiration or termination of this agreement. In addition, the warranties of merchantability and fitness for a particular purpose are disclaimed. In addition, Bayer Diagnostics shall not be liable for any damages caused by delay in providing repair service from any cause. Bayer Diagnostics liability for breach of this warranty shall be limited to the repair or replacement of defective equipment and shall not include any incidental, contingent, or consequential damages.

Supplies and Accessories

Use Table B-1 and Table B-2 to find the supply or accessary you need to order.

Table B-1. Supplies and Accessories

Part Number	Description
115701	*Manual, Rapidlab 800 Operator's*
115713	Manual, *Rapidlab 800 Quick Reference Guide*, English
115716	Manual, *Rapidlab 800 Quick Reference Guide*, Spanish
115719	Manual, *Rapidlab 800 Quick Reference Guide*, French
115722	Manual, *Rapidlab 800 Quick Reference Guide*, Italian
115710	*Manual, Rapidlab 800 Interface Specification*
106363	Brochure, Specimen Collection for Critical Blood Analyte™ Testing
673709000	Printer Paper
473385000	Buffer 7.382 (7.3/CO-ox Zero Buffer)
473386000	Buffer 6.838
473387000	Wash G/L Zero Reagent
570096	Cal G/L Reagent
473389000	Cleaning Solution 1 and Cleaning Solution 2 (C1/C2)
478701000	Conditioner Kit (5 pack)
473643000	Deproteinizer Kit (5 pack)
105610	Deproteinizer Kit (10 pack)
476282000	Test/Blank Sensor pO_2/pCO_2 (TB1)
476281000	Test/Blank Sensor pH/Na^+ (TB2)
673701000	Test/Blank Sensor Glucose and Lactate (TB4)

(Continued)

Part Number	Description
673702000	Test/Blank Sensor $K^+/Ca^{++}/Cl^-$ (TB3)
673396000	Test/Blank Sensor Ref (TB5)
477832000	Ticket Printer
478736000	Fuse Kit
477570000	Clot Removal Kit
673703000	Aspiration Adapter Kit
858040001	Power Cord, US
858071001	Power Cord, International
111399	Kit Bar Code Scanner LS4004
110889	Bar Code Scanner (LS4004)
110890	Cable, Bar Code Scanner (LS4004)
858086001	Cable, Bar Code Scanner (LS2020)
673715000	Air (Dust) Filter
673712000	Capillary Seal
013896701	Sample Door Kit (Luer)
673357000	Drip Tray Kit
673714000	Sample Probe
673704000	Sample Tubing
673705000	Pump Tubing Kit
014448701	Measurement Module Tubing Kit
014738001	Sample Connector (Sample Tee Adapter)
104794	Reagent Manifold Vent Filter Kit (2 filters per kit)

(Continued)

Part Number	Description
013895701	Reagent Fitting Kit (Septum Probe)
673708000	Lamp Bulb (incandescent)
014073002	9-pin Cable-Matching Connector
013899001	Loopback Connector
013902701	O-ring Kit
013903701	Blank 3.5-inch Diskette, Preformatted
673356000	Waste Bottle Kit
476267000	pH Ready Sensor
476247000	pCO_2 Ready Sensor
476246000	pO_2 Ready Sensor
476270000	Potassium Ready Sensor
476266000	Sodium Ready Sensor
476268000	Calcium Ready Sensor
476279000	Chloride Ready Sensor
476378000	Glucose Ready Sensor
476379000	Lactate Ready Sensor
476273000	Reference Sensor
471854000	Arterial Blood Sampler (3 mL, 17 USP units lithium heparin per mL)
473395000	850 to 860 Upgrade Kit
473396000	840 to 860 Upgrade Kit
473397000	840 to 850 Upgrade Kit
478509000	Reference Sensor Internal (internal electrode, fill solution)

(Continued)

Part Number	***Description***
478498000	Reference Sensor Refill (cassette, fill solution, O-rings)
013174001	Retainer, Sample Port
013186001	Sample Port
013199001	Front Cover
477833000	Analysis Report Ticket
477434000	Cal Calibration Gas (5% CO_2, 12% O_2)
477438000	Slope Calibration Gas (10% CO_2)
823736001	Gas Tank Seal
478740000	Sample Ground/Temperature Sensor
013662001	Waste Nozzle (waste outlet cover)
014117701	Cable, 800 to 270 Interface
014118001	9-pin to 25-pin Cable Adapter
014374001	Alphanumeric Keyboard

Table B-2. Supplies and Accessories for the CO-ox Module

Part Number	Description
473120000	CO-oximeter Slope (10 pack)
570017	CO-ox Air Filter
570051	CO-ox Pump Tubing
014801001	CO-ox Pump Tubing Connector
570019	CO-ox Sample Tubing Kit
570050	CO-ox Lamp
570018	CO-ox O-ring/Gasket Kit (for hemolyzer and sample chamber)
673700000	Clot Removal Kit (tubing diameter <0.022mm)
570049	Sample Chamber
106371	Bubble Trap Kit
015552701	CO-ox Spares Kit
570018	CO-ox O-ring/Gasket Kit
570052	Anvil Kit
014607002	Anvil Cap
014734002	Cam 1
014735002	Cam 2
823851001	Wave Spring (fits behind assembled Cam 1 and 2)

Appendix C: References

This appendix lists all references for this manual.

1. National Committee for Clinical Laboratory Standards. Blood Gas Pre–Analytical Considerations: Specimen Collection, Calibration and Controls, Approved Guideline; NCCLS Document C–27A (Vol. 13, No. 6); April 1993.
2. Douglas IHS, McKenzie PJ, Leadingham I, Smith G. Effect of halothane h. on pO_2 electrode. Lancet 1978; (Dec. 23 and 30).
3. National Committee for Clinical Laboratory Standards. Clinical Laboratory Waste Management; Approved Guideline; NCCLS Document GP5–A; (Vol. 13, No. 22); Dec 1993.
4. U.S. Dept. of Health and Human Services. Health Care Financing Administration Public Health Service. 42 CFR Part 405, Subpart K, et al, Federal Register: Clinical Improvement Amendments of 1988; Final Rule. Washington, D.C.: GPO, 1992.
5. National Committee for Clinical Laboratory Standards. Statistical Quality Control for Quantitative Measurements: Principles and Definitions, Approved Guideline – Second Edition; NCCLS Document C24–A; (Vol. 19, No. 5); Feb 1999.
6. Selby, Samuel M., editor. CRC standard mathematical tables. Cleveland (OH): The Chemical Rubber Co., 1971.
7. National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue; Approved Guideline; NCCLS Document M29–A; (Vol 17, No. 20); Dec 1997.
8. National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue; Approved Guideline; NCCLS Document M29–A; (Vol 17, No. 20); Dec 1997.
9. Kirchhoff JR, Wheeler JF, Lunte CE, Heineman WR. Electrochemistry: principles and measurements. In: Kaplan LA, Pesce AJ., editors. Clinical Chemistry: theory, analysis, and correlation. 2nd ed. St. Louis: CV Mosby, 1989. 213–227.
10. Siggaard-Andersen O. Electrochemistry. In: Tietz NW, editor. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders, 1987. 87–101.
11. Siggaard-Anderson O, Durst RA, Maas AHJ. Physicochemical quantities and units in clinical chemistry with special emphasis on activities and activity coefficients. Pure Appl Chem 1984; 56: 567–594.
12. National Committee for Clinical Laboratory Standards. Standardization of Sodium and Potassium Ion–Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard; NCCLS Document C29–A; (Vol. 15, No. 1); Mar 1995.
13. Sorensen, SPL. Enzymstudien. ii, uber die messung and die bedeutung der wasserstoffionenkonzentration bei enzymatischen prozessen. Biochem Z 1909; 12:131.

14. Moran R, Cormier A. The blood gases: pH, pO_2, pCO_2. Clin Chem News 1988; 14(4/5): 10–12.

15. Severinghaus JW, Bradley AF. Electrodes for blood pO_2 and pCO_2 determination. J Appl Physiol 1968; 13:515–520.

16. Shapiro BA, Harrison RA, Cane RD, Templin R. Clinical application of blood gases. 4th ed. Chicago: Year Book Medical Publishers, 1989. 270–272.

17. Clark LC Jr. Monitor and control of blood and tissue oxygen tensions. Trans Am Soc Artif Intern Organs 1956; 2:41–56.

18. Pagana KD, Pagana TJ. Diagnostic testing and nursing implications. 3rd ed. St. Louis: CV Mosby, 1990. 448–449.

19. Mundy GR. Calcium homeostasis – the new horizons. In: Moran RF, editor. Ionized calcium: its determination and clinical usefulness. Proceedings of an international symposium. Galveston (TX): The Electrolyte Blood Gas Division of the American Association for Clinical Chemistry, 1986: 1–4.

20. Ladenson JH. Clinical utility of ionized calcium. In: Moran RF, editor. Ionized calcium: its determination and clinical usefulness. Proceedings of an international symposium. Galveston (TX): The Electrolyte Blood Gas Division of the American Association for Clinical Chemistry, 1986: 5–11.

21. Ravel R. Clinical Laboratory Medicine. 3rd ed. Chicago: Year Book Medical Publishers, 1978; 273–281.

22. National Committee for Clinical Laboratory Standards. Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard; NCCLS Document C12–A; (Vol. 14, No. 11); Sept 1994.

23. VanSlyke DD, Cullen GE. Studies of acidosis 1. The bicarbonate concentration of blood plasma, its significance and its determination as a measure of acidosis. J Biol Chem 1917; 30:289–346.

24. Kelman GR. Digital computer subroutine for the conversion of oxygen tension into saturation. J Appl Physiol 1966; 21:1375–1376.

25. Thomas LJ. Algorithms for selected blood acid-base and blood gas calculations. J Appl Physiol 1972; 33:154–158.

26. National Committee for Clinical Laboratory Standards. Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline; NCCLS Document C25–A; (Vol. 17, No. 3); Jan 1997.

27. Miale JB. Laboratory medicine hematology. 6th edition. St. Louis: CV Mosby; 1982. 608.

28. Martin L. Abbreviating the alveolar gas equation: an argument for simplicity. Respir Care 1985; 30(11):964–967.

29. Aberman A, Cavanilles JM, Trotter J, Erbeck D, Weil MH,Shubin H. J Appl Physiol 1935; 4: 570–571.

30. Peris LV, Boix JH, Salom JV, Valentin V, et al. Clinical use of the arterial/alveolar oxygen tension ratio. Crit Care Med 1983; 11(11):888–891.

31. Burritt MF, Cormier AD, Maas AHJ, Moran RF, O'Connell KM. Methodology and clinical applications of ion-selective electrodes. Proceedings of an international symposium. Danvers (MA): The Electrolyte/Blood Gas Division of the American Association of Clinical Chemistry, 1987.

32. Aberman A, Cavanille JM, Trotter J, Erbeck D, Weil MH, Shubin H. An equation for the oxygen hemoglobin dissociation curve. J Appl Physiol 1973; 35(4):570–571.

33. National Committee for Clinical Laboratory Standards. Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard; NCCLS Document C12–A; (Vol. 14, No. 11); Sept 1994.

34. Moran RF, Fallon KD. Oxygen saturation, content, and the dyshemoglobins: part I. Clin Chem News, 16:1, 11, 1990.

35. VanAssendelft OW. Spectrophotometry of hemoglobin derivatives. The Netherlands: Thomas, 1970:47–65.

36. VanAssendelft OW, Zijlstra WG. Extinction coefficients for use in equations for the spectrophotometric analysis of hemoglobin mixtures. Anal Biochem 1975;69:43–48.

37. Benesch RE, Benesch R, Yung S. Equations for the spectrophotometric analysis of hemoglobin mixtures. Anal Biochem 1973; 55:245–248.

38. Miale JB. Laboratory medicine hematology. 6th ed. St. Louis: CV Mosby, 1982:388–392.

39. National Committee for Clinical Laboratory Standards. Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline; NCCLS Document C25–A; (Vol. 17, No. 3); Jan 1997.

40. Miale JB. Laboratory medicine hematology. 6th ed. St. Louis: CV Mosby, 1982:456–464.

41. Cooper HA, Hoagland JC. Fetal hemoglobin. Mayo Clin Proc 1972; 47(6):402–414.

42. National Committee for Clinical Laboratory Standards. Clinical Laboratory Waste Management; Approved Guideline; NCCLS Document GP5–A; (Vol. 13, No. 22); Dec 1993.

43. Spurzem JR, Bonekat Hw, Shigeoka JW. Factitious methemoglobinemia caused by hyperlipemia. Chest 1984; 86(7): 84–86.

44. Young DS, Pestaner LC, Gibberman V. Effects of drugs on clinical laboratory tests. Clin Chem 1975; 21(5): 315D–329D.

45. National Committee for Clinical Laboratory Standards. Preparation and testing of reagent water in the clinical laboratory; Approved Guideline; NCCLS Document C3–A3; (Vol. 17, No. 18); Oct 1997.

46. National Committee for Clinical Laboratory Standards. Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline; NCCLS Document C25–A; (Vol. 17, No. 3); Jan 1997.

47. Malley W. Clinical blood gases: application and noninvasive alternatives. Philadelphia: WB Saunders, 1990; 95.

48. Shapiro BA, Harrison RA, Cane RD, Kozlowski–Templin R. Clinical application of blood gases. 4th ed. Chicago: Year Book Medical Publishers, 1989: 143.

49. Shapiro BA, Harrison RA, Cane RD, Kozlowski–Templin R. Clinical application of blood gases. 4th ed. Chicago: Year Book Medical Publishers, 1989: 140.

50. Malley W. Clinical blood gases: application and noninvasive alternatives. Philadelphia: WB Saunders, 1990; 97–98.

51. Shapiro BA, Harrison RA, Cane RD, Kozlowski–Templin R. Clinical application of blood gases. 4th ed. Chicago: Year Book Medical Publishers, 1989: 144.

52. Shapiro BA, Harrison RA, Cane RD, Kozlowski–Templin R. Clinical application of blood gases. 4th ed. Chicago: Year Book Medical Publishers, 1989: 159.

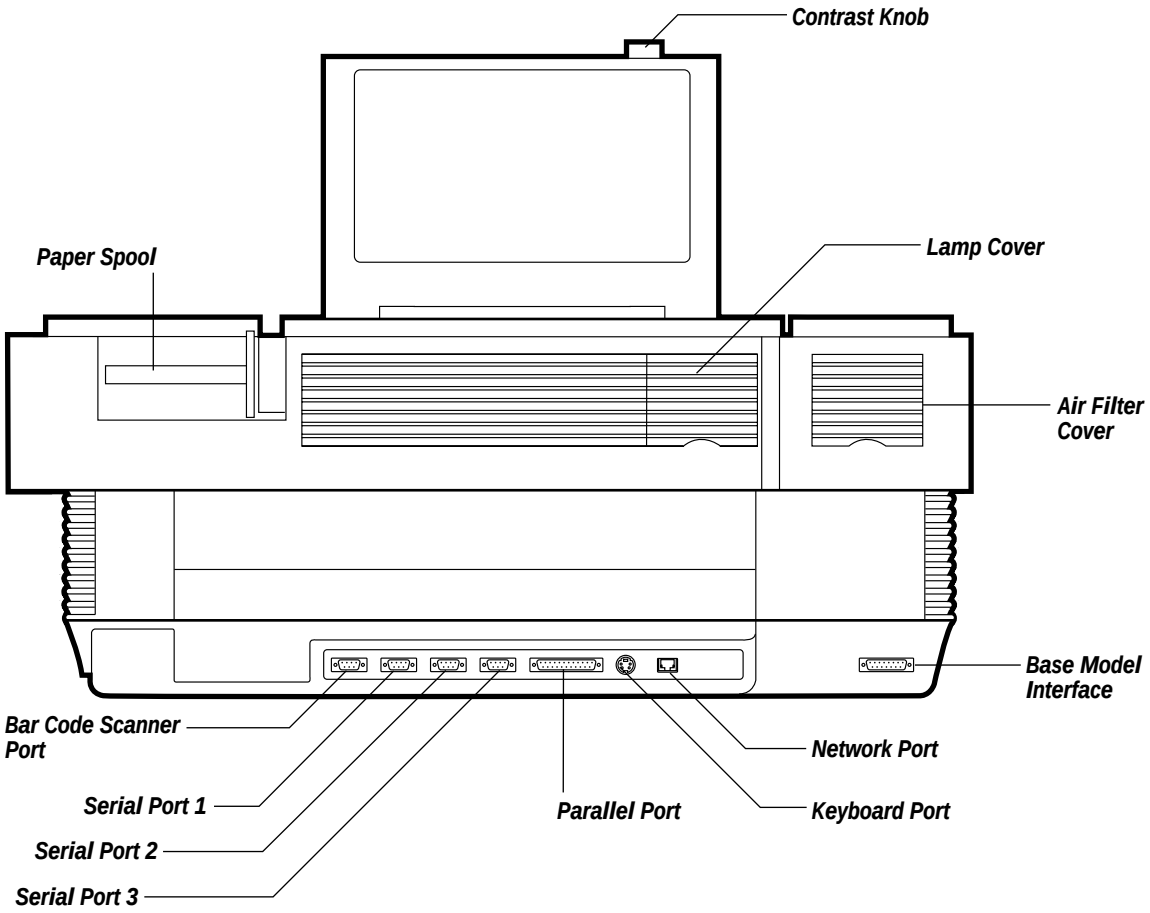
Appendix D: Connecting to External Devices

This section provides information about making the connection between an 800 series system and the following external devices:

- 270 CO-oximeter
- 800 series compatible ticket printer
- bar code scanner
- Bayer Diagnostics data management system
- line printer
- laboratory information system (LIS)
- hospital information system (HIS)

Figure D-1 identifies the various ports available on the 800 system.

Figure D-1. Rear View



Connecting to a 270 CO-oximeter

Use this procedure to connect an 800 system to a 270 CO-oximeter.

Materials Required:

- 800 to 270 interface cable (part number 014117701)

WARNING To prevent electrical shock and damage to either system, disconnect the 800 system and 270 CO-oximeter from the AC power source before installing the cable. Refer to *Shutting Down and Restarting the System* in Section 5 for the procedure to disconnect the 800 system.

1. Disconnect the 800 system from the AC power source.
2. Disconnect the 270 CO-oximeter from the AC power source.
3. Connect the 9-pin connecter of the interface cable to serial port 2 or 3 on the 800 system. Refer to Figure D-1.
4. Connect the 25-pin connector to port 1, 2, or 3 on the 270.
5. Tighten the hold down screws on the connectors.
6. Restore power to the 800 system and to the 270.
7. Refer to *Configuring for External Devices* in Section 5 to configure the 800 system for the 270.
8. Refer to *Configuring a 270 CO-oximeter* in Section 6 of the *270 CO-oximeter Operator's Manual* to configure the 270 for the 800 system.
9. Define the setup at the 270 CO-oximeter:
   a. At the Main Menu, press the right arrow key two times, and press **SETUP**.
   b. Press the right arrow key two times, and press **INTERFACES**.
   c. Press **PORT NO**.

      The port numbers 1, 2 and 3 correspond to the port labels on the 270 rear panel.
   d. Enter the number of the serial port to which the interface cable is connected, and press **ENTER**.
   e. Press the right arrow key twice, and select **LIS3**.

f. Press **ENTER** to confirm your selection.

g. Select the transmission specifications as shown in Table D-1.

Table D-1. 270 Communication Parameters

Parameter	*Setting*
baud rate	9600
parity	even
stop bit	1
data bits	8
modem control	no

h. Press **ENTER** to confirm the selections.

The display shows the port number and the device connected to the port.

i. Press **CONTINUE** to return to the **Select INTERFACES setup option** prompt. The printer prints the port number and the device type connected to the port.

10. Refer to *Defining the Auto Send Option* in Section 6 of the *270 CO-oximeter Operator's Manual* to specify whether the 270 automatically sends results as soon as they are available or whether the operator can select the results to transmit.

Connecting to the Ticket Printer

Use this procedure to connect an 800 system to the 800 series compatible ticket printer.

Materials Required:

- ticket printer (part number 477832)
- 800 system to ticket printer interface cable (part number 014116701)

WARNING To prevent electrical shock and damage to either system, disconnect the 800 system and the printer from the AC power source before installing the cable. Refer to *Shutting Down and Restarting the System* in Section 5 for the procedure to disconnect the 800 system.

1. Disconnect the 800 system from the AC power source.
2. Disconnect the printer from the AC power source.

NOTE: Always use serial port 1 for the ticket printer.

3. Connect the 9-pin connector of the interface cable to serial port 1 on the 800 system. Refer to Figure D-1.
4. Connect the 25-pin connector to the printer.
5. Tighten the hold down screws on the connectors.
6. Restore power to the 800 system and to the printer.
7. Refer to *Configuring for External Devices* in Section 5 to configure the 800 system for the printer and to *Selecting Printing Options* in Section 5 to select the ticket printer as the printer used to print reports.

Connecting the Bar Code Scanner

Use this procedure to connect an 800 system to the 800 bar code scanner.

Materials Required:

- bar code scanner
- 800 system to bar code scanner cable

WARNING To prevent electrical shock and damage to either system, disconnect the 800 system from the AC power source before installing the bar code scanner. Refer to *Shutting Down and Restarting the System* in Section 5 for the procedure to disconnect the 800 system.

1. Disconnect the 800 system from the AC power source.
2. Connect the 9-pin connector of the bar code scanner to the bar code scanner port on the 800 system. Refer to Figure D-1.
3. Tighten the hold down screws on the connectors.
4. Restore power to the 800 system.
5. Refer to *Configuring for External Devices* in Section 5 to configure the 800 system for the bar code scanner.

Connecting to a Bayer Diagnostics Data Management System

Use this procedure to connect the 800 system to a Bayer Diagnostics data management system.

Materials Required:

- data management to 800 system to interface cable (supplied with the data management system)

WARNING To prevent electrical shock and damage to either system, disconnect the 800 system and the data management system from the AC power source before installing the cable. Refer to *Shutting Down and Restarting the System* in Section 5 for the procedure to disconnect the 800 system.

1. Disconnect the 800 system from the AC power source.
2. Disconnect the computer for the data management system from the AC power source.
3. Connect the interface cable to serial port 2 or 3 on the 800 system and to the Bayer Diagnostics data management system. Refer to Figure D-1.
4. Tighten the hold down screws on the connectors.
5. Restore power to the 800 system and the computer for the data management system.
6. Refer to *Configuring for External Devices* in Section 5 to configure the 800 system for the data management system.

Connecting to a Line Printer

Use this procedure to connect an 800 system to a line printer.

Materials Required:

- printer to 800 system interface cable for a parallel port (supplied with printer)

WARNING To prevent electrical shock and damage to either instrument, disconnect the 800 system and the printer from the AC power source before installing the cable. Refer to *Shutting Down and Restarting the System* in Section 5 for the procedure to disconnect the 800 system.

1. Disconnect the 800 system from the AC power source.
2. Disconnect the printer from the AC power source.
3. Connect the interface cable to the line printer and to the parallel port on the 800 system. Refer to Figure D-1.
4. Restore power to the 800 system and to the line printer.
5. Refer to *Configuring for External Devices* in Section 5 to configure the 800 system for the line printer.

Connecting to a Laboratory or Hospital Information System

Use this procedure to connect an 800 system to a laboratory information system (LIS) or hospital information system (HIS).

Materials Required:

- LIS or HIS to 800 system interface cable and 9-pin, cable-matching connector (supplied with the LIS or HIS)
- if you are converting from a 200 series system, 9-pin to 25-pin cable adapter (part number 014118001)

WARNING To prevent electrical shock and damage to either system, disconnect the 800 system and Data Management system from the AC power source before installing the cable. Refer to *Shutting Down and Restarting the System* in Section 5 for the procedure to disconnect the 800 system.

1. Contact your LIS or HIS system manager to determine the appropriate interface cable.
2. Disconnect the 800 system from the AC power source.
3. Connect the interface cable to serial port 2 or 3 on the 800 system and to the LIS or HIS. Refer to Figure D-1.
4. Tighten the hold down screws on the connectors.
5. Restore power to the 800 system.
6. Refer to *Configuring for External Devices* in Section 5 to configure the 800 system for the LIS or HIS.
7. Refer to the *800 Series Interface Specification Manual* to configure the LIS or HIS for the 800 system.

Appendix E: Performance Characteristics

This appendix provides the following information about the 800 series systems:

- system specifications
- limitations
- reference methods
- 840 system performance characteristics
- 850 system performance characteristics
- 860 system performance characteristics
- CO-ox module performance characteristics

System Specifications

Table E-1 lists the specifications for the 800 system.

Table E-1. System Specifications

Property	*Specification*
ambient operating temperature	15 – 32°C
ambient operating relative humidity	5 – 85%, non-condensing
power rating	400VA
voltage requirements	100V/120V (85V to 132V) 50/60Hz 220V/240V (170V to 264V) 50/60Hz
ambient operating barometric pressure	400 – 825 mmHg (53.0 – 110.0 kPa)
system dimensions, base model	height 50.8 cm (20 inches) width 55.9 cm (22 inches) depth 48.3 cm (19 inches) weight 29.5 kg (65 lbs)
system dimensions, CO-ox module	height 30.3 cm (11.94 inches) when installed 47.8 cm (18.81 inches) width 17.35 cm (6.83 inches) when installed 70.3 cm (27.66 inches) depth 50.3 cm (19.81 inches) weight 7.9 kg (17.5 lbs) when installed 36.5 kg (82 lbs)

Table E-2 lists the units, reporting ranges, and display resolutions for the pH and blood gas parameters measured by the 800 system.

Table E-2. pH and Blood Gas Parameters

Parameter	Units	Reporting Range	Resolution High	Low
pH	pH	6.000 – 8.000	0.001	0.01
H^+	nmol/L	10.0 – 1000.0	0.1	1
pCO_2	mmHg	5.0 – 250.0	0.1	1
	kPa	0.67 – 33.33	0.01	0.1
pO_2	mmHg	0 – 800	0.1	1
	kPa	0.0 – 106.67	0.01	0.1
*p*Atm	mmHg	400 – 825	1	1
	kPa	53.3 – 110.0	0.1	0.1

Table E-3 lists the units, reporting ranges, and display resolutions for the electrolyte parameters measured or calculated by the 850 and 860 systems.

Table E-3. Electrolyte and Metabolite Parameters

Parameter	Units	Reporting Range	Resolution
Na^+	mmol/L	70.0 – 200.0	0.1
K^+	mmol/L	0.50 – 9.99	0.01
	mmol/L	10.0 – 20.0	0.1
Ca^{++}	mmol/L	0.25 – 5.00	0.01
	mg/dL	1.0 – 20.0	0.1
$Ca^{++}(7.4)$	mmol/L	0.10 – 5.70	0.01
	mg/dL	0.4 – 22.8	0.1
Cl^-	mmol/L	40 – 160	1
Glucose	mg/dL	10 – 999	1
	mmol/L	0.6 – 55.4	0.1

(Continued)

Parameter	Units	Reporting Range	Resolution
Lactate	mg/dL	0.0 – 270.3	0.1
	mmol/L	0.00 – 30.00	0.01
AnGap	mmol/L	–5.0 – 50.0	0.1

Table E-4 lists the units, reporting ranges, and display resolutions for the oxygenation parameters calculated by the 800 system or calculated from a sample analyzed on the 800 system and a connected CO-oximeter.

Table E-4. Oxygenation Parameters

Parameter	Units	Reporting Range	Resolution
*p*50	mmHg	15.0 – 75.0	0.1
	kPa	2.00 –10.00	0.01
ctO_2	mL/dL	0 – 40.0	0.1
	mL/L	0 – 400	1
	mmol/L	0 – 17.8	0.1
ctO_2(a)	mL/dL	0 – 40.0	0.1
	mL/L	0 – 400	1
	mmol/L	0 – 17.8	0.1
ctO_2(v)	mL/dL	0 – 40.0	0.1
	mL/L	0 – 400	1
	mmol/L	0 – 17.8	0.1
O_2SAT(est)	%	0.0 – 100.0	0.1
	decimal fraction	0.0 – 1.000	0.001
O_2CT(est)	mL/dL	0 – 40.0	0.1
	mL/L	0 – 400	1
	mmol/L	0 – 17.8	0.1

(Continued)

Parameter	Units	Reporting Range	Resolution
ctO_2(a-v)	mL/dL	0.0 – 20.0	0.1
	mL/L	0 – 200	1
	mmol/L	0.0 – 9.0	0.1
ctO_2([a-v]/a))	%	0 – 100	1
	decimal fraction	0.00 – 1.00	0.01
VO_2	mL/min	0 – 3500	1
	L/min	0.00 – 3.50	0.01
	mmol/min	0 – 156.2	0.1
DO_2	mL/min	0 – 3500	1
	L/min	0.00 – 3.50	0.01
	mmol/min	0 – 156.2	0.1

Table E-5 lists the units, reporting ranges, and display resolutions for parameters measured by the 800 system CO-ox module.

Table E-5. CO-ox Module Parameters

Parameter	Units	Reporting Range	Resolution
tHb	g/dL	2.0 – 27.0	0.1
	g/L	20 – 270	1
	mmol/L	1.2 – 16.8	0.1
FO_2Hb	fraction	–0.999– 9.999	0.001
	%	–99.9 – 999.9	0.1
sO_2	fraction	–0.999– 9.999	0.001
	%	–99.9 – 999.9	0.1
*F*COHb	fraction	–0.999– 9.999	0.001

(Continued)

Parameter	Units	Reporting Range	Resolution
	%	–99.9 – 999.9	0.1
*F*MetHb	fraction	–0.999 – 9.999	0.001
	%	–99.9 – 999.9	0.1
*F*HHb	fraction	–0.999 – 9.999	0.001
	%	–99.9 – 999.9	0.1
BO_2 (O_2CAP)	mL/dL	0.0 – 40.0	0.1
	mL/L	0 – 400	1
	mmol/L	0.0 – 17.8	0.1
p50	mmHg	15.0 – 75.0	0.1
	kPa	2.00 – 10.00	0.01
*c*tO_2(Hb)	mL/dL	0 – 40.0	0.1
	mL/L	0 – 400	1
	mmol/L	0 – 17.8	0.1

Table E-6 lists the units, reporting ranges, and display resolutions for the temperature corrected and respiratory parameters calculated by the 800 system.

Table E-6. Temperature Corrected and Respiratory Parameters

Parameter	Units	Reporting Range	Resolution
pH(T)	pH	6.000 – 8.000	0.001
H^+(T)	nmol/L	10.0 – 316.3	0.1
pCO_2(T)	mmHg	5.0 – 250.0	0.1
	kPa	0.67 – 33.33	0.01
pO_2(T)	mmHg	0 – 800	0.1
	kPa	0 – 106.67	0.01

(Continued)

Parameter	Units	Reporting Range	Resolution
pO_2(A–a)(T)	mmHg	0 – 800.0	0.1
	kPa	0 – 106.67	0.01
pO_2(a/A)(T)	%	0 – 100	1
	decimal fraction	0.00 – 1.00	0.01
RI(T)	%	0 – 2000	1
	decimal fraction	0.00 – 20.00	0.01
Qsp/Qt(T)	%	0 – 100	1
	decimal fraction	0.00 – 1.00	0.01
Qsp/Qt(est, T)	%	0 – 100	1
	decimal fraction	0.00 – 1.00	0.01

Table E-7 lists the units, reporting ranges, and display resolutions for the metabolic parameters calculated by the 800 system.

Table E-7. Metabolic Parameters

Parameter	Units	Reporting Range	Resolution
HCO_3^-act	mmol/L	0 – 99.9	0.1
HCO_3^-std	mmol/L	0 – 99.9	0.1
$ctCO_2$	mmol/L	0 – 99.9	0.1
BE(B)	mmol/L	±29.9	0.1
BE(ecf)	mmol/L	±29.9	0.1

Table E-8 lists the units, reporting ranges, and display resolutions for the parameters that can be entered into the 800 system.

Table E-8. Entered Parameters

Parameter	*Units*	*Reporting Range*	*Resolution*
Temperature	°C	10.0 – 43.9	0.1
	°F	50.0 – 111.0*	0.1
F_IO_2	%	15.0 – 100.0	0.1
	decimal fraction	0.150 – 1.000	0.001
*c*tHb	g/dL	2.0 – 27.0	0.1
	g/L	20 – 270	1
	mmol/L	1.3 – 16.8	0.1
OBF		1.35 – 1.40	0.01
Flow	L/min	0.00 – 99.99	0.01
Resp Rate	b/min	0.0 – 100.0	0.1
*p*50	mmHg	15.0 – 75.0	0.1
	kPa	2.00 – 10.00	0.01
Qt	L/min	0.00 – 30.0	0.01

* The 800 system converts Fahrenheit values to centigrade values.

Reference Methods

The following reference methods were used for the 800 systems.

Analyte	Reference Method
pH	IFCC reference method,* also referenced by NCCLS document C–27A.[1]
pCO_2 and pO_2	Tonometered whole blood as described in NCCLS document C21–A.† Gases used are traceable to NIST Certified Reference Material SRM series 1701.
Na^+ and K^+	Method described in NCCLS document C29[12], which serves as the basis for the NIST Certified Reference Material SRM 956 using flame photometry.
Cl^-	Coulometric reference method. This method, which is embodied in the Bayer Diagnostics 925, is also used to assign values to NIST Certified Reference Material SRM 956.
Ca^{++}	Internal method used.
Glucose	The hexokinase/glucose-6-phosphate dehydrogenase method described in NCCLS document RS1–A.‡
Lactate	LD Manual Assay
tHb	Cyanmethemoglobin Reference Method per National Committee for Clinical Laboratory Standards (NCCLS), approved reference procedure‖ using Cary 4 Spectrophotometer.
FO_2Hb	Tonometry, where whole blood samples are tonometered with 95% O_2, 5% CO_2.
*F*HHb	Tonometry, where whole blood samples are tonometered with 95% N_2, and 5% CO_2.
*F*COHb	Gas Chromatography§ for COHb ≤ 15% and Ishizawa# method using a Cary 4 Spectrophotometer for COHb ≤ 15%
*F*MetHb	Modified Evelyn–Malloy[37] method utilizing a Cary 4 Spectrophotometer.

* International Federation of Clinical Chemistry. Reference method (1986) for pH measurement in blood. IFCC 1987/3.

† National Committee for Clinical Laboratory Standards. Performance characteristics for devices measuring PO_2 and PCO_2 in blood samples; Approved Standard; NCCLS Document C21–A; (Vol 12, No. 3); March 1992.

‡ National Committee for Clinical Laboratory Standards. Glucose; Approved Summary of Methods and Materials; NRSCL Document RS1–A; 1998.

§ Vreman, H.J., Kwong, L.K., and Stevenson, D.K., Carbon Monoxide in Blood: an Improved Microliter Blood-Sample Collection System, with Rapid Analysis by Gas Chromatography, Clin. Chem.30, (1382 - 1386) 1984.

‖ National Committee for Clinical Laboratory Standards. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood – Second Edition; Approved Standard; NCCLS Document H15–A; (Vol 14, No. 6); May 1994.

Ishizawa F. A Study on the Spectrophotometric Determination of Carboxyhemoglobin in Blood — Isobestic Point Method. Jpn J Legal Med 1981, 35(3), 191–200.

Limitations

Bayer Diagnostics cannot guarantee system performance when any of the following situations occur. Specific terms of warranty, service, and contract agreements may be invalidated if any of these situations occur.

- Reagents other than those recommended are used.
- Expiration dates of reagents have been exceeded.
- Reagents are not used according to Bayer Diagnostics recommendations.
- Standard laboratory practices are not followed.
- The procedures described in this manual are not followed.
- Environmental operating conditions and location recommendations are not followed.

840 System Performance Characteristics

All performance data presented in this section were generated using 840 systems. The system used default correlation factors, and performed calibrations using the default settings recommended by Bayer Diagnostics for optimum performance. All reported values were corrected to 760 mmHg. The operating environment during the collection of this data was normal room temperature (about 23°C).

You should determine your own performance characteristics in your laboratory with your 840 system.

Precision on Controls

Quality control (QC) materials and calibration verification materials (CVM) were analyzed on the 840 systems. The results are presented here.

Precision on aqueous quality control materials was estimated using three 840 systems. At least seven runs per instrument were made over five days. Two replicates of each control level were analyzed in each run.

Table E-9 summarizes the results of the 840 system precision on QC materials.

Table E-9. 840 QC Precision Results

Parameter	*Level*	*n*	*Mean*	*WRSD**	*TotSD†*
pH6.5	1	48	7.165	0.001	0.002
	2	48	7.426	0.001	0.002
	3	46	7.623	0.001	0.002
pCO_2	1	48	71.7	0.50	1.27
	2	48	44.1	0.12	0.63
	3	46	22.4	0.12	0.56
pO_2	1	48	57.6	1.20	1.67
	2	48	100.7	0.75	1.77
	3	46	149.1	1.11	2.31

* WRSD = within-run standard deviation

† TotSD = total standard deviation

Precision on aqueous calibration verification materials was estimated using three 840 systems. At least seven runs per instrument were made over five days. Two replicates of each control level were analyzed in each run.

Table E-10 summarizes the results of the 840 system precision for CVM levels 1 and 4.

Table E-10. 840 CVM Precision Results

Parameter	*Level*	*n*	*Mean*	*WRSD**	*TotSD*†
pH	1	50	6.804	0.001	0.002
	4	50	7.804	0.001	0.002
pCO_2	1	50	103.9	0.67	1.73
	4	50	12.8	0.21	0.52
pO_2	1	50	24.3	0.72	1.81
	4	50	249.9	2.06	5.11

* WRSD = within-run standard deviation

† TotSD = total standard deviation

Recovery and Precision with Whole Blood and Expired Gases

For testing syringe, capillary, microsyringe, and microcapillary modes, blood was collected in heparinized vacuum tubes. It was tonometered at 37.0°C to each of three levels to prepare samples for pH analysis and five levels to prepare samples for pCO_2 and pO_2 analysis. Multiple runs were made using these samples on three 840 systems. The experimental protocol called for three replicates of each level in each run.

For testing the expired gas mode, 10 mL of tonometry gas were drawn into a 12 mL syringe and aspirated into the 840 system for analysis. Multiple runs were made using five levels of expired gas on four 840 instruments. The experimental protocol called for three replicates of each level in each run.

Table E-11 through Table E-13 summarize the results of the 840 system whole blood and expired gas recovery precision testing.

Table E-11. 840 Recovery and Precision Testing—pH

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	15	0.002	7.251	7.251	100.0
	Capillary	12	0.003	7.255	7.258	100.0
	Microcapillary	17	0.006	7.261	7.256	100.1
	Microsyringe	18	0.003	7.248	7.238	100.1
	pH Only	15	0.004	7.235	7.235	100.0
2	Syringe	12	0.003	7.427	7.420	100.1
	Capillary	14	0.003	7.429	7.423	100.1
	Microcapillary	12	0.004	7.380	7.374	100.1
	Microsyringe	15	0.002	7.400	7.397	100.0
	pH Only	12	0.007	7.411	7.410	100.0
3	Syringe	15	0.002	7.663	7.654	100.1
	Capillary	12	0.002	7.656	7.650	100.1
	Microcapillary	18	0.007	7.664	7.664	100.0
	Microsyringe	18	0.003	7.651	7.645	100.1
	pH Only	15	0.004	7.636	7.635	100.0

* WRSD = within-run standard deviation

Table E-12. 840 Recovery and Precision Testing—pCO_2

Level	*Mode*	*n*	*WRSD**	*Observed*	*Expected*	*Recovery*
1	Syringe	24	0.08	14.0	14.3	98.0
	Capillary	18	0.32	13.6	14.3	95.1
	Microcapillary	24	0.34	14.0	14.3	97.6
	Microsyringe	24	0.13	14.3	14.3	99.9
	Expired Gas	24	0.10	14.5	14.3	101.4
2	Syringe	24	0.14	21.6	21.4	100.8
	Capillary	18	0.17	21.4	21.4	100.0
	Microcapillary	24	0.45	21.4	21.4	100.2
	Microsyringe	24	0.15	21.6	21.4	101.2
	Expired Gas	24	0.14	21.6	21.4	100.7
3	Syringe	24	0.22	35.8	35.7	100.4
	Capillary	18	0.53	35.3	35.7	98.8
	Microcapillary	23	0.77	36.2	35.7	101.3
	Microsyringe	24	0.30	35.7	35.7	99.9
	Expired Gas	24	0.25	35.5	35.7	99.4
4	Syringe	24	0.28	50.1	49.9	100.3
	Capillary	18	0.40	51.3	49.9	102.8
	Microcapillary	24	1.28	51.5	49.9	103.2
	Microsyringe	24	0.21	50.3	49.9	100.8
	Expired Gas	24	0.37	49.4	49.9	99.0
5	Syringe	24	0.26	71.5	71.3	100.3

(Continued)

Level	Mode	n	WRSD*	Observed	Expected	Recovery
	Capillary	18	0.68	71.7	71.3	100.6
	Microcapillary	24	2.24	71.0	71.3	99.5
	Microsyringe	24	0.33	71.4	71.3	100.1
	Expired Gas	24	0.17	71.1	71.3	99.7

* WRSD = within-run standard deviation

Table E-13. 840 Recovery and Precision Testing—pO_2

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.21	28.2	28.5	99.1
	Capillary	18	0.40	28.3	28.5	99.3
	Microcapillary	24	1.15	29.0	28.5	101.7
	Microsyringe	24	0.17	28.6	28.5	100.3
	Expired Gas	24	0.15	28.2	28.5	98.8
2	Syringe	24	0.19	50.0	49.9	100.3
	Capillary	18	0.23	50.5	49.9	101.2
	Microcapillary	24	0.71	49.0	49.9	98.3
	Microsyringe	24	0.15	49.7	49.9	99.6
	Expired Gas	24	0.14	49.7	49.9	99.7
3	Syringe	24	0.66	86.6	85.6	101.2
	Capillary	18	0.36	84.8	85.6	99.1
	Microcapillary	23	1.11	86.2	85.6	100.7
	Microsyringe	24	1.08	85.8	85.6	100.3
	Expired Gas	24	0.15	85.5	85.6	99.9

(Continued)

Level	Mode	n	WRSD*	Observed	Expected	Recovery
4	Syringe	24	0.97	150.5	149.7	100.5
	Capillary	18	0.86	150.2	149.7	100.3
	Microcapillary	24	2.00	151.8	149.7	101.4
	Microsyringe	24	0.80	150.6	149.7	100.6
	Expired Gas	24	0.25	150.4	149.7	100.5
5	Syringe	24	1.20	377.9	377.9	100.0
	Capillary	18	2.40	379.0	377.9	100.3
	Microcapillary	24	4.08	380.7	377.9	100.7
	Microsyringe	24	3.22	378.9	377.9	100.3
	Expired Gas	24	0.66	378.7	377.9	100.2

* WRSD = within-run standard deviation

850 System Performance Characteristics

All performance data presented in this section was generated using 850 systems. The system used default correlation factors, and performed calibrations using the default settings recommended by Bayer Diagnostics for optimum performance. All reported values were corrected to 760 mmHg. The operating environment during the collection of this data was normal room temperature (about 23°C).

You should determine your own performance characteristics in your laboratory with your 850 system.

Precision on Controls

Quality control materials and calibration verification materials were analyzed on the 850 systems. The results are presented here.

Precision on aqueous quality control materials was estimated using four 850 systems. At least seven runs per instrument were made over ten days. Two replicates of each control level were analyzed in each run.

Table E-14 summarizes the results of the 850 system precision on QC materials.

Table E-14. 850 QC Precision Results

Parameter	Level	n	Mean	WRSD*	TotSD†
pH	1	72	7.169	0.002	0.002
	2	71	7.428	0.001	0.003
	3	72	7.623	0.001	0.002
pCO_2	1	72	71.5	0.43	1.01
	2	71	44.1	0.21	0.58
	3	72	22.6	0.13	0.38
pO_2	1	72	58.3	2.64	3.25
	2	71	98.2	1.93	3.32
	3	72	142.2	1.90	2.92
Na^+	1	72	113.1	0.20	0.81

(Continued)

Parameter	Level	n	Mean	WRSD*	TotSD†
	2	71	133.0	0.21	0.86
	3	72	154.5	0.36	1.58
K^+	1	72	2.42	0.007	0.023
	2	71	4.96	0.017	0.036
	3	72	7.71	0.022	0.087
Cl^-	1	72	79.2	0.35	0.57
	2	71	101.7	0.27	0.53
	3	72	121.6	0.29	0.92
Ca^{++}	1	72	1.54	0.006	0.012
	2	71	1.12	0.005	0.011
	3	72	0.62	0.004	0.009

* WRSD = within-run standard deviation

† TotSD = total standard deviation

Precision on aqueous calibration verification materials was estimated using four 850 systems. As many as seven runs per instrument were made over seven days. Two replicates of each control level were analyzed in each run.

Table E-15 summarizes the results of the 850 system precision for CVM levels 1 and 4.

Table E-15. 850 CVM Precision Results

Parameter	Level	n	Mean	WRSD*	TotSD†
pH	1	44	6.806	0.001	0.004
	4	44	7.805	0.002	0.004
pCO_2	1	44	103.5	0.93	1.49
	4	44	13.4	0.13	0.28

(Continued)

Parameter	Level	n	Mean	WRSD*	TotSD†
pO_2	1	44	25.8	1.39	1.97
	4	44	237.7	2.99	5.78
Na^+	1	44	102.4	0.34	1.31
	4	44	167.2	0.48	1.43
K^+	1	44	2.04	0.059	0.073
	4	44	16.87	0.170	0.235
Cl^-	1	44	132.1	0.95	1.22
	4	44	75.9	0.47	0.52
Ca^{++}	1	44	2.82	0.035	0.056
	4	44	0.55	0.009	0.017

* WRSD = within-run standard deviation

† TotSD = total standard deviation

Recovery and Precision with Whole Blood and Expired Gases

For testing syringe, capillary, microsyringe, and microcapillary modes, blood was collected in heparinized vacuum tubes. It was tonometered at 37.0°C to each of three levels to prepare samples for pH analysis, and five levels to prepare samples for pCO_2 and pO_2 analysis. Blood was spiked/diluted to each of three levels to prepare samples for sodium, potassium, calcium, and chloride analysis. Multiple runs were made using these samples on four 850 systems. The experimental protocol called for three replicates of each level in each run.

For testing the expired gas mode, 10 mL of tonometry gas were drawn into a 12 mL syringe and aspirated into the 850 system for analysis. Multiple runs were made using five levels of expired gas on four 850 instruments. The experimental protocol called for three replicates of each level in each run.

Table E-16 through Table E-22 summarize the results of the 850 system whole blood, expired gas, and electrolyte recovery and precision testing.

Table E-16. 850 Recovery and Precision Testing—pH

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.002	7.194	7.193	100.0
	Capillary	24	0.003	7.194	7.194	100.0
	Microcapillary	24	0.003	7.170	7.175	99.9
	Microsyringe	24	0.002	7.229	7.225	100.1
	pH/Lytes	18	0.003	7.220	7.218	100.0
2	Syringe	24	0.001	7.399	7.405	99.9
	Capillary	24	0.002	7.397	7.393	100.1
	Microcapillary	24	0.003	7.402	7.396	100.1
	Microsyringe	24	0.002	7.383	7.397	99.8
	pH/Lytes	18	0.004	7.357	7.356	100.0
3	Syringe	24	0.004	7.493	7.493	100.0
	Capillary	24	0.003	7.502	7.505	100.0
	Microcapillary	24	0.006	7.449	7.459	99.9
	Microsyringe	24	0.003	7.557	7.560	100.0
	pH/Lytes	18	0.005	7.673	7.676	100.0

* WRSD = within-run standard deviation

Table E-17. 850 Recovery and Precision Testing—pCO_2

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.28	14.0	14.3	97.9
	Capillary	24	0.08	14.7	14.3	102.5
	Microcapillary	24	0.20	14.5	14.3	101.7
	Microsyringe	24	0.14	14.1	14.3	98.7
	Expired Gas	24	0.14	14.5	14.3	101.6
2	Syringe	21	0.12	21.3	21.4	99.7
	Capillary	24	0.12	21.5	21.4	100.5
	Microcapillary	18	0.59	20.7	21.4	96.9
	Microsyringe	18	0.42	21.3	21.4	99.4
	Expired Gas	18	0.77	21.0	21.4	98.3
3	Syringe	18	0.43	35.1	35.7	98.2
	Capillary	24	0.25	36.4	35.7	102.0
	Microcapillary	18	0.50	34.5	35.7	96.6
	Microsyringe	18	0.34	35.9	35.7	100.7
	Expired Gas	18	0.30	34.9	35.7	97.8
4	Syringe	24	0.72	50.5	49.9	101.3
	Capillary	24	0.29	48.4	49.9	97.1
	Microcapillary	24	0.47	51.1	49.9	102.4
	Microsyringe	24	0.21	49.9	49.9	100.0
	Expired Gas	24	0.26	49.9	49.9	100.1
5	Syringe	21	1.13	71.7	71.3	100.5

(Continued)

Level	Mode	n	WRSD*	Observed	Expected	Recovery
	Capillary	24	1.20	71.7	71.3	100.6
	Microcapillary	18	1.36	71.1	71.3	99.7
	Microsyringe	18	0.55	70.5	71.3	98.9
	Expired Gas	18	0.49	71.0	71.3	99.6

* WRSD = within-run standard deviation

Table E-18. 850 Recovery and Precision Testing—pO_2

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	21	0.16	28.2	28.5	98.9
	Capillary	21	0.18	28.9	28.5	101.4
	Microcapillary	18	0.35	29.0	28.5	101.8
	Microsyringe	18	0.25	28.5	28.5	100.2
	Expired Gas	18	0.16	27.9	28.5	98.0
2	Syringe	24	0.22	50.5	49.9	101.2
	Capillary	18	0.34	49.2	49.9	98.6
	Microcapillary	24	0.41	49.4	49.9	99.0
	Microsyringe	24	0.13	49.8	49.9	99.8
	Expired Gas	24	0.10	49.4	49.9	99.1
3	Syringe	18	0.34	85.3	85.6	99.6
	Capillary	22	0.33	85.5	85.6	99.9
	Microcapillary	18	0.99	84.5	85.6	98.7
	Microsyringe	18	0.70	85.6	85.6	100.0
	Expired Gas	18	0.20	84.7	85.6	98.9

(Continued)

Level	*Mode*	*n*	*WRSD**	*Observed*	*Expected*	*Recovery*
4	Syringe	18	2.65	149.6	149.7	99.9
	Capillary	22	0.83	150.0	149.7	100.2
	Microcapillary	18	0.98	150.0	149.7	100.2
	Microsyringe	18	0.62	149.4	149.7	99.8
	Expired Gas	18	0.31	149.5	149.7	99.8
5	Syringe	21	1.40	377.4	377.9	99.9
	Capillary	21	2.41	377.5	377.9	99.9
	Microcapillary	18	5.50	378.9	377.9	100.3
	Microsyringe	17	5.51	377.5	377.9	99.9
	Expired Gas	17	1.55	379.2	377.9	100.3

* WRSD = within-run standard deviation

Table E-19. 850 Recovery and Precision Testing—Na^+

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.25	115.6	115.5	100.1
	Capillary	24	0.29	115.6	115.5	100.1
	Microcapillary	24	0.47	115.1	115.1	100.0
	Microsyringe	24	0.42	115.4	115.3	100.1
	pH/Lytes	24	0.43	121.0	120.9	100.1
2	Syringe	24	0.49	150.9	151.0	99.9
	Capillary	24	0.46	150.9	151.2	99.8
	Microcapillary	24	0.80	151.2	151.1	100.0
	Microsyringe	24	0.49	151.0	151.3	99.8
	pH/Lytes	24	0.75	151.3	151.6	99.7
3	Syringe	24	0.39	174.2	174.2	100.0
	Capillary	24	0.39	174.3	174.1	100.1
	Microcapillary	24	1.81	173.9	173.9	100.0
	Microsyringe	24	0.45	174.1	173.9	100.1
	pH/Lytes	24	1.33	170.4	170.2	100.2

* WRSD = within-run standard deviation

Table E-20. 850 Recovery and Precision Testing—K^+

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.071	1.89	1.90	99.3
	Capillary	24	0.050	1.89	1.88	100.6
	Microcapillary	24	0.092	1.88	1.83	102.3
	Microsyringe	24	0.043	1.79	1.83	97.7
	pH/Lytes	24	0.029	1.95	1.95	99.8
2	Syringe	24	0.020	3.49	3.51	99.5
	Capillary	24	0.034	4.14	4.14	100.0
	Microcapillary	24	0.037	3.81	3.78	100.7
	Microsyringe	24	0.016	3.81	3.82	99.7
	pH/Lytes	24	0.013	3.74	3.74	100.2
3	Syringe	24	0.109	7.21	7.23	99.8
	Capillary	24	0.126	7.43	7.38	100.7
	Microcapillary	24	0.139	7.21	7.27	99.2
	Microsyringe	24	0.079	7.33	7.28	100.7
	pH/Lytes	24	0.131	6.44	6.45	100.0

* WRSD = within-run standard deviation

Table E-21. 850 Recovery and Precision Testing—Ca^{++}

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	21	0.007	0.78	0.76	102.5
	Capillary	24	0.011	0.79	0.77	102.1
	Microcapillary	24	0.025	0.80	0.75	106.4
	Microsyringe	21	0.014	0.72	0.74	97.6
	pH/Lytes	18	0.016	0.78	0.76	103.2
2	Syringe	21	0.012	1.87	1.84	102.0
	Capillary	24	0.017	1.85	1.82	101.8
	Microcapillary	24	0.010	1.65	1.65	99.7
	Microsyringe	21	0.008	1.66	1.58	104.8
	pH/Lytes	18	0.023	1.64	1.57	104.5
3	Syringe	21	0.028	2.48	2.46	101.2
	Capillary	24	0.035	2.56	2.56	100.2
	Microcapillary	24	0.077	2.21	2.26	97.6
	Microsyringe	21	0.026	2.20	2.14	102.8
	pH/Lytes	18	0.042	2.13	2.12	100.6

* WRSD = within-run standard deviation

Table E-22. 850 Recovery and Precision Testing—Cl^-

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.4	88	88	99.6
	Capillary	24	0.6	88	89	99.7
	Microcapillary	24	0.8	88	89	99.5
	Microsyringe	24	0.6	89	89	99.8
	pH/Lytes	24	0.6	91	90	100.2
2	Syringe	24	0.7	117	116	100.5
	Capillary	24	0.3	117	116	100.5
	Microcapillary	24	1.1	117	116	100.8
	Microsyringe	24	0.6	116	116	100.4
	pH/Lytes	24	1.4	118	119	99.6
3	Syringe	24	0.5	140	141	99.9
	Capillary	24	0.5	141	141	99.8
	Microcapillary	24	2.7	141	142	99.7
	Microsyringe	24	0.7	141	141	99.8
	pH/Lytes	24	2.1	140	140	100.2

* WRSD = within-run standard deviation

860 System Performance Characteristics

All performance data presented in this section was generated using 860 systems. The system used default correlation factors, and performed calibrations using the default settings recommended by Bayer Diagnostics for optimum performance. All reported values were corrected to 760 mmHg. The operating environment during the collection of this data was normal room temperature (about 23°C).

You should determine your own performance characteristics in your laboratory with your 860 system.

Glucose Biosensor Interfering Substances

To test for interferences, serum was spiked with a potentially interfering substance up to the test concentration shown in the following two tables. The interference was calculated by comparing the spiked sample to an unspiked sample immediately preceding it. To evaluate the interference from fluoride/oxalate, the blood was drawn in grey-top tubes and compared to the glucose recovery in heparinized blood.

Table E-23 lists substances that were found not to interfere with the glucose measurement. At the concentrations listed, these compounds produced less than 6 mg/dL (0.3 mmol/L) error in the recovered glucose concentration.

Table E-23. Substances Showing No Interference

Substance	*Concentration Tested*
Chlorpromazine	5 mg/dL
Dopamine	0.5 mg/dL*
Ethanol	350 mg/dL
Salicylate	50 mg/dL
Sodium Nitroprusside	70 mg/dL
Citrate	1000 U/dL
Heparin	20,000 U/dL
Acetoacetate	40 mg/dL
Ascorbate	6 mg/dL

(Continued)

Substance	Concentration Tested
Thiocyanate	80 mg/dL
Bilirubin (Direct)	30 mg/dL
Bilirubin (Total)	34 mg/dL
Creatinine	30 mg/dL
Hydroxybutyrate	200 mg/dL
Lactate	100 mg/dL
Urea	500 mg/dL
Uric Acid	10 mg/dL

* Interference by dopamine and structurally related drugs is dependent on glucose concentration. However, even at high glucose concentrations, therapeutic levels of dopamine do not interfere with the glucose measurement.

The following anticoagulants were found not to interfere with glucose recovery at the indicated concentrations but they cannot be used on the 860 system due to potential interferences on other sensors or analytes.

Table E-24. Potential Interference on Other Analytes

Substance	Concentration Tested
Citrate	1000 mg/dL
Potassium Oxalate	1000 mg/dL

Refer to *Sample Collection Devices and Anticoagulants* in Section 1 for the specific requirements on sample handling and anticoagulants.

Table E-25 lists substances that interfere with the glucose measurement.

Table E-25. Substances Interfering with the Glucose Measurement

Substance	***Concentration Tested***	***Level of Interference****
Sodium Fluoride	1000 mg/dL each	25 mg/dL (1.4 mmol/L)
Acetominophen	2 mg/dL	7 mg/dL (0.4 mmol/L)
Sodium Fluoride/ Potassium Oxalate	1000 mg/dL each	25 mg/dL (1.4 mmol/L)

* Increased reported glucose values by the amount shown.

Lactate Biosensor Interfering Substances

To test for interferences, serum was spiked with a potentially interfering substance up to the test concentration shown in the following tables. The interference was calculated by comparing the spiked sample to an unspiked sample immediately preceding it. To evaluate the interference from fluoride/oxalate, the blood was drawn in grey-top tubes and compared to the lactate recovery in heparinized blood.

The following table lists substances that were found not to interfere with the lactate measurement. At the concentrations listed, these compounds produced less than 0.3 mmol/L (2.7 mg/dL) error in the recovered lactate concentration.

Table E-26. Substances Showing No Detectable Interference

Substance	Concentration Tested
Chlorpromazine	17 mg/dL
Dopamine	1 mg/dL
Ethanol	350 mg/dL
Salicylate	50 mg/dL
Sodium Nitroprusside	70 mg/dL
Thiocyanate	80 mg/dL
Heparin	20,000 U/dL
Epinephrine	2 mg/dL
Norepinephrine	2 mg/dL
Phenobarbital	15 mg/dL
Glutamate	16 mg/dL
Hetastarch	30%
Acetoacetate	40 mg/dL
Ascorbate	8 mg/dL
Dilantin	14 mg/dL

(Continued)

Substance	Concentration Tested
Bilirubin (Direct)	30 mg/dL
Bilirubin (Total)	35 mg/dL
Creatinine	30 mg/dL
Glucose	1000 mg/dL
Hydroxybutyrate	200 mg/dL
Urea	500 mg/dL
Guaiacol	5 mg/dL
Pyruvate	9 mg/dL
Theophylline	9 mg/dL
Penicillamine	25 mg/dL
Isoniazid	2 mg/dL
Uric Acid	10 mg/dL

The following anticoagulants were found not to interfere with lactate recovery at the indicated concentrations but they cannot be used on the 860 system due to potential interferences on other sensors or analytes.

Table E-27. Substances with Potential Interference with Other Analytes

Substance	Concentration Tested
Citrate	1000 mg/dL
Potassium Oxalate	1000 mg/dL
EDTA	800 mg/dL

Refer to *Sample Collection Devices and Anticoagulants* in Section 1 for the specific requirements on sample handling and anticoagulants.

Table E-28. Substances Interfering with the Lactate Measurement

Substance	Concentration Tested	Level of Interference
Sodium Fluoride	1000 mg/dL	1 mmol/L (9 mg/dL)
Sodium Fluoride/ Potassium Oxalate	1000 mg/dL	1 mmol/L (9 mg/dL)
Acetominophen	2 mg/dL	0.35 mmol/L (3.2 mg/dL)

Precision on Controls

Quality control materials and calibration verification materials were analyzed on the 860 systems. The results are presented here.

Precision on aqueous quality control materials was estimated using fifteen 860 systems. Seventeen runs per instrument were made over a twenty-two day period. Two replicates of each control level were analyzed in each run.

For glucose, precision on aqueous calibration verification materials was estimated using fifteen 860 systems. Data from seven to sixteen runs per instrument were available. The data were collected over a two-month period. Two replicates of each control level were analyzed in each run.

For lactate, precision on aqueous calibration verification materials was estimated using fifteen 860 systems. Six runs per instrument were made over an eight day period. Two replicates of each control level were analyzed in each run.

Table E-29 summarizes the results of the 860 system precision on QC materials.

Table E-29. 860 QC Precision Results

Parameter	Level	n	Mean	WRSD*	TotSD†
pH6.5	1	387	7.157	0.002	0.004
	2	316	7.423	0.001	0.004
	3	235	7.617	0.003	0.006
pCO_2	1	293	72.5	1.12	1.87

(Continued)

Parameter	Level	n	Mean	WRSD*	TotSD†
	2	241	43.0	0.89	1.41
	3	185	23.0	0.64	0.81
pO_2	1	387	61.7	1.79	2.17
	2	316	103.5	1.46	2.66
	3	236	152.3	1.89	4.51
Na^+	1	387	112.7	0.25	0.62
	2	316	135.1	0.21	0.50
	3	236	151.3	0.40	0.77
K^+	1	387	2.68	0.014	0.020
	2	316	5.04	0.014	0.022
	3	236	7.34	0.033	0.050
Cl^-	1	387	119.5	0.57	1.14
	2	316	100.0	0.34	0.74
	3	236	77.6	0.41	0.57
Ca^{++}	1	386	1.47	0.006	0.011
	2	316	1.12	0.004	0.007
	3	236	0.59	0.004	0.008
Glu‡	1	387	37.73	0.795	1.157
	2	316	103.5	1.585	2.165
	3	236	212.6	2.743	4.570
Lactate	1	183	11.27	0.404	0.433

(Continued)

Parameter	Level	n	Mean	WRSD*	TotSD†
	2	177	0.99	0.011	0.049
	3	170	0.52	0.008	0.033

* WRSD = within-run standard deviation

† TotSD = total standard deviation

‡ Performance determined with metabolite recal on. Refer to *Glucose Biosensor Calibration*, in Section 1 for information on performance with recal off.

Table E-30 summarizes the results of the 860 system precision for CVM levels 1 and 4.

Table E-30. 860 CVM Precision Results

Parameter	Level	n	Mean	WRSD*	TotSD†
pH	1	565	6.782	0.002	0.004
	4	551	7.830	0.007	0.009
pCO_2	1	575	107.6	1.48	3.11
	4	548	13.0	0.37	0.74
pO_2	1	563	26.0	1.63	2.02
	4	539	249.0	6.05	8.36
Na^+	1	592	89.6	0.65	1.25
	4	560	166.1	0.75	1.32
K^+	1	592	1.44	0.036	0.052
	4	563	15.34	0.177	0.315
Cl^-	1	586	134.2	0.95	2.48
	4	560	73.0	0.85	1.17
Ca^{++}	1	592	2.75	0.038	0.065
	4	560	0.51	0.012	0.017

* WRSD = within-run standard deviation

† TotSD = total standard deviation

Recovery and Precision with Whole Blood and Expired Gases

For testing syringe, capillary, microsyringe, and microcapillary modes, blood was collected in heparinized vacuum tubes. It was tonometered at 37.0°C to each of three levels to prepare samples for pH analysis, and five levels to prepare samples for pCO_2 and pO_2 analysis. Blood was spiked/diluted to each of three levels to prepare samples for sodium, potassium, calcium, chloride glucose and lactate analysis. Multiple runs were made using these samples on four 860 systems, except for lactate. For lactate, multiple runs were made on six 860 systems. The experimental protocol called for three replicates of each level in each run.

For testing the expired gas mode, 10 mL of tonometry gas were drawn into a 12 mL syringe and aspirated into the 860 system for analysis. Multiple runs were made using five levels of expired gas on four 860 systems. The protocol called for three replicates of each level in each run.

Table E-31 through Table E-44 summarize the results of the 860 system whole blood, expired gas, and electrolyte recovery and precision testing.

Table E-31. 860 Recovery and Precision Testing—pH

Level	Mode	n	WRSD*	Observed	Expected	Recovery
7.21	Syringe	48	0.002	7.213	7.214	100.0
	Capillary	48	0.004	7.202	7.202	100.0
	Microcapillary	48	0.003	7.205	7.205	100.0
	Microsyringe	48	0.002	7.204	7.205	100.0
	pH/Lyte	48	0.003	7.207	7.208	100.0
7.37	Syringe	48	0.002	7.373	7.369	100.1
	Capillary	44	0.002	7.376	7.375	100.0
	Microcapillary	48	0.006	7.376	7.376	100.0
	Microsyringe	48	0.002	7.371	7.370	100.0
	pH/Lyte	48	0.002	7.361	7.363	100.0
7.52	Syringe	48	0.003	7.544	7.546	100.0

(Continued)

Level	Mode	n	WRSD*	Observed	Expected	Recovery
	Capillary	48	0.004	7.507	7.502	100.1
	Microcapillary	36	0.005	7.529	7.526	100.0
	Microsyringe	48	0.004	7.503	7.500	100.0
	pH/Lyte	36	0.003	7.507	7.507	100.0

Table E-32. 860 Recovery and Precision Testing—pCO_2

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.20	14.5	14.3	101.5
	Capillary	24	0.15	14.4	14.3	100.4
	Microcapillary	24	0.19	14.3	14.3	100.0
	Microsyringe	24	0.10	14.2	14.3	99.5
	Expired Gas	18	0.09	14.7	14.3	102.9
2	Syringe	24	0.12	21.8	21.4	101.7
	Capillary	24	0.19	21.6	21.4	100.9
	Microcapillary	24	0.33	21.6	21.4	101.2
	Microsyringe	24	0.28	22.1	21.4	103.1
	Expired Gas	24	0.16	21.5	21.4	100.3
3	Syringe	24	0.41	35.0	35.7	98.0
	Capillary	24	0.44	35.2	35.7	98.5
	Microcapillary	24	0.25	35.6	35.7	99.7
	Microsyringe	24	0.31	35.2	35.7	98.7
	Expired Gas	24	0.11	35.2	35.7	98.6
4	Syringe	24	0.52	50.0	49.9	100.2

(Continued)

Level	Mode	n	WRSD*	Observed	Expected	Recovery
	Capillary	23	0.44	50.3	49.9	100.8
	Microcapillary	24	0.71	49.9	49.9	100.0
	Microsyringe	24	0.54	49.8	49.9	99.7
	Expired Gas	18	0.62	49.4	49.9	99.1
5	Syringe	24	0.52	71.3	71.3	100.1
	Capillary	24	0.82	71.2	71.3	99.8
	Microcapillary	24	1.07	71.0	71.3	99.5
	Microsyringe	24	1.46	71.0	71.3	99.5
	Expired Gas	24	0.24	70.5	71.3	98.8

* WRSD = within-run standard deviation

Table E-33. 860 Recovery and Precision Testing—pO_2

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.21	28.5	28.5	99.9
	Capillary	24	0.25	28.5	28.5	100.1
	Microcapillary	24	0.44	28.6	28.5	100.4
	Microsyringe	24	0.33	28.7	28.5	100.7
	Expired Gas	24	0.12	28.0	28.5	98.1
2	Syringe	24	0.35	50.2	49.9	100.6
	Capillary	23	0.23	49.9	49.9	100.1
	Microcapillary	24	0.38	50.0	49.9	100.2
	Microsyringe	24	0.49	49.7	49.9	99.6
	Expired Gas	24	0.56	49.8	49.9	99.7

(Continued)

Level	Mode	n	WRSD*	Observed	Expected	Recovery
3	Syringe	24	1.19	84.9	85.6	99.2
	Capillary	24	0.61	85.4	85.6	99.7
	Microcapillary	24	0.80	84.8	85.6	99.0
	Microsyringe	24	1.08	85.2	85.6	99.5
	Expired Gas	24	0.09	85.4	85.6	99.8
4	Syringe	24	1.34	150.0	149.7	100.2
	Capillary	24	0.87	150.0	149.7	100.2
	Microcapillary	24	2.04	150.1	149.7	100.2
	Microsyringe	24	0.95	150.6	149.7	100.6
	Expired Gas	24	0.19	150.0	149.7	100.2
5	Syringe	24	1.52	378.8	377.9	100.2
	Capillary	24	1.55	378.7	377.9	100.2
	Microcapillary	24	4.69	378.9	377.9	100.3
	Microsyringe	24	2.35	379.6	377.9	100.5
	Expired Gas	24	0.39	377.5	377.9	99.9

* WRSD = within-run standard deviation

Table E-34. 860 Recovery and Precision Testing—Na^+

Level	Mode	n	WRSD*	Observed	Expected	Recovery
119.4	Syringe	24	0.30	119.8	120.2	99.7
	Capillary	24	1.33	120.0	119.8	100.2
	Microcapillary	36	0.76	116.3	117.7	98.8
	Microsyringe	24	0.47	119.4	120.3	99.2

(Continued)

Level	Mode	n	WRSD*	Observed	Expected	Recovery
	pH/Lyte	21	0.42	117.8	119.1	98.9
148.7	Syringe	24	0.63	149.2	149.9	99.5
	Capillary	24	0.44	149.0	149.7	99.5
	Microcapillary	36	0.98	147.1	147.4	99.9
	Microsyringe	33	0.58	148.3	148.4	99.9
	pH/Lyte	24	0.57	148.4	148.6	99.9
171.5	Syringe	24	0.38	172.1	171.6	100.3
	Capillary	24	1.25	171.6	171.2	100.2
	Microcapillary	36	2.44	171.7	171.2	100.3
	Microsyringe	24	0.97	172.3	172.0	100.2
	pH/Lyte	21	1.08	171.9	171.4	100.3

* WRSD = within-run standard deviation

Table E-35. 860 Recovery and Precision Testing—K^+

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1	Syringe	24	0.043	1.37	1.39	97.2
	Capillary	24	0.095	1.34	1.38	96.2
	Microcapillary	24	0.145	1.67	1.73	96.4
	Microsyringe	24	0.032	1.53	1.62	92.8
	pH/Lyte	24	0.060	1.66	1.66	100.4
2	Syringe	48	0.028	3.75	3.73	100.6
	Capillary	48	0.027	3.72	3.69	100.7
	Microcapillary	48	0.027	3.63	3.66	99.3
	Microsyringe	48	0.038	3.78	3.78	100.2
	pH/Lyte	48	0.022	3.54	3.51	100.9
3	Syringe	24	0.142	8.47	8.57	98.9
	Capillary	24	0.106	8.51	8.42	101.1
	Microcapillary	24	0.164	8.43	8.48	99.3
	Microsyringe	24	0.223	8.37	8.36	100.1
	pH/Lyte	24	0.193	8.45	8.51	99.3

* WRSD = within-run standard deviation

Table E-36. 860 Recovery and Precision Testing—Ca^{++}

Level	Mode	n	WRSD*	Observed	Expected	Recovery
0.69	Syringe	48	0.008	0.70	0.69	102.3
	Capillary	48	0.016	0.72	0.70	102.3
	Microcapillary	48	0.017	0.71	0.69	102.6
	Microsyringe	48	0.009	0.71	0.69	103.2
	pH/Lyte	48	0.013	0.71	0.68	104.3
1.66	Syringe	48	0.014	1.67	1.65	100.8
	Capillary	44	0.011	1.66	1.65	100.5
	Microcapillary	48	0.026	1.67	1.65	100.9
	Microsyringe	48	0.014	1.67	1.67	100.4
	pH/Lyte	48	0.022	1.66	1.66	100.1
2.38	Syringe	48	0.036	2.42	2.39	101.2
	Capillary	48	0.061	2.37	2.37	100.0
	Microcapillary	48	0.049	2.38	2.40	99.2
	Microsyringe	48	0.039	2.35	2.36	99.7
	pH/Lyte	48	0.034	2.39	2.40	99.9

* WRSD = within-run standard deviation

Table E-37. 860 Recovery and Precision Testing—Cl^-

Level	Mode	n	WRSD*	Observed	Expected	Recovery
86	Syringe	24	0.4	86	87	99.7
	Capillary	24	1.1	87	86	100.4
	Microcapillary	36	1.3	84	85	99.1
	Microsyringe	24	1.0	86	86	100.2
	pH/Lyte	24	0.6	86	87	99.2
117	Syringe	24	0.6	116	117	98.9
	Capillary	24	1.0	118	118	100.3
	Microcapillary	36	1.0	117	116	100.2
	Microsyringe	36	1.2	116	117	99.4
	pH/Lyte	24	0.6	117	117	99.5
142	Syringe	24	1.2	141	142	99.8
	Capillary	24	1.7	142	142	100.1
	Microcapillary	36	2.9	141	141	99.6
	Microsyringe	24	1.4	141	142	99.5
	pH/Lyte	24	1.7	142	142	100.2

* WRSD = within-run standard deviation

Table E-38. 860 Recovery and Precision Testing—Glucose*

Level	Mode	n	WRSD†	Observed	Expected	Recovery
45	Syringe	39	0.9	47	46	102.8
	Capillary	30	1.4	46	43	107.9
	Microcapillary	30	1.8	44	43	101.2
	Microsyringe	36	1.2	45	45	100.6
	pH/Lyte	21	1.6	47	47	100.7
81	Syringe	33	2.1	85	84	100.6
	Capillary	33	1.4	85	83	102.5
	Microcapillary	36	2.5	79	79	99.8
	Microsyringe	45	1.9	84	82	102.3
	pH/Lyte	24	1.1	81	80	101.1
207	Syringe	33	3.5	205	205	100.4
	Capillary	33	2.9	206	203	101.5
	Microcapillary	36	3.9	206	205	100.8
	Microsyringe	45	3.8	205	203	101.2
	pH/Lyte	23	3.1	206	205	100.6

* Performance determined with metabolite recal on. Refer to *Glucose Biosensor Calibration* in Section 1 for information on performance with recal off.

† WRSD = within-run standard deviation

Table E-39. 860 Recovery and Precision Testing—Lactate

Level	Mode	n	WRSD*	Observed	Expected	Recovery
1.75	Syringe	36	0.030	1.69	1.61	105.2
	Capillary	36	0.062	1.83	1.79	102.3
	Microcapillary	36	0.089	1.65	1.73	95.4
	Microsyringe	36	0.028	1.75	1.70	103.3
	pH/Lyte	35	0.075	2.11	1.90	110.7
2.81	Syringe	36	0.046	2.83	2.89	98.1
	Capillary	36	0.074	2.67	2.80	95.4
	Microcapillary	36	0.145	2.69	2.73	98.6
	Microsyringe	35	0.057	2.70	2.84	95.1
	pH/Lyte	36	0.066	2.73	2.79	98.0
3.94	Syringe	18	0.019	3.80	3.64	104.3
	Capillary	36	0.112	4.19	3.90	107.3
	Microcapillary	36	0.189	3.93	3.92	100.3
	Microsyringe	36	0.046	4.10	3.95	103.8
	pH/Lyte	36	0.107	4.44	4.22	105.2

* WRSD = within-run standard deviation

CO-ox Module Performance Characteristics

All performance data presented in this section was generated using the 800 system CO-ox modules. The system performed recommended tHb slope procedures, and calibrations using the default settings recommended by Bayer Diagnostics for optimum performance. The operating environment during collection of this data was normal room temperature (about 23°C).

You should determine your own performance characteristics in your laboratory with your 800 system.

CO-ox Module Interfering Substances

To test for interferences, blood was spiked with an interfering substance up to the test concentration shown in the following two tables. The interference was calculated by comparing the average difference between the spiked and unspiked samples.

Any substance that absorbs light in the same regions as whole blood could potentially cause an interference.

Table E-40. Interference Criteria for Absolute Difference of Spiked and Unspiked Samples

Analyte	*Criteria*
tHb	<0.5 g/dL
O_2Hb	<1.0%
COHb	<1.0%
MetHb	<1.0%
HHb	<1.0%

Table E-41 lists substances that were found not to interfere using the criteria stated in Table E-40.

Table E-41. Substances Showing No Detectable Interference

Substance	*Level*
Indocyanine Green	5 mg/L
Lipid	equivalent to 3% intralipid
Bilirubin	20 mg/dL
Fetal Hemoglobin	at 21%

Table E-42 lists substances that showed interference using the criteria stated in Table E-40.

Table E-42. Substances Showing Interference

Substance	*Interferes with . . .**	*Level of Interference*
Evans Blue at 5 mg/L	O_2Hb	–2.1%
	MetHb	+1.4%
Methylene Blue at 25 mg/L	O_2Hb	–3.3%
	HHb	+2.7%
Cyanmethemoglobin at 10 %	O_2Hb	–1.8%
	MetHb	–1.3%
	HHb	+2.3%
Sulfhemoglobin at 10%	O_2Hb	+3.3%
	MetHb	–3.3%
Fetal Hemoglobin at 40%	COHb	+1.5%
	HHb	–1.3%

(Continued)

Substance	Interferes with . . .*	Level of Interference
Fetal Hemoglobin at 80%	tHb	–0.9 g/dL
	COHb	+3.1%
	MetHb	–1.1%
	HHb	–2.6%
Carboxymethylcellulose	tHB	–2.0 g/dL
	COHb	+10.0%
	O_2Hb	–10.0%
	HHb	+6.5%

* Analytes that are within interference criteria stated in Table E-40 are not listed.

Precision on Controls

Quality control materials were analyzed on the 800 series CO-ox module. The results are presented here.

Precision on aqueous quality control materials was estimated using four 800 systems. One run per instrument was made over a eight day period. Three replicates of each control level were analyzed in each run.

Table E-43 summarizes the results of the 800 CO-ox module precision on QC materials.

Table E-43. 800 CO-ox Module Precision Results

Parameter	Level	n	Mean	WRSD*	TotSD†
tHb	1	96	9.36	0.05	0.25
	2	96	13.98	0.07	0.37
	3	96	21.60	0.08	0.54
FO_2Hb	1	96	5.79	0.11	0.28
	2	96	13.56	0.18	0.30
	3	96	22.01	0.22	0.30

(Continued)

Parameter	Level	n	Mean	WRSD*	TotSD†
*F*COHb	1	96	52.64	0.18	0.35
	2	96	32.03	0.16	0.30
	3	96	9.52	0.35	0.39
*F*MetHb	1	96	5.05	0.13	0.23
	2	96	4.70	0.14	0.24
	3	96	4.07	0.19	0.30
*F*HHb	1	96	36.52	0.30	0.44
	2	96	49.71	0.25	0.36
	3	96	64.40	0.30	0.41

* WRSD = within-run standard deviation

† TotSD = total standard deviation

Recovery and Precision with Whole Blood

For testing syringe and capillary modes, blood was collected in heparinized vacuum tubes. It was tonometered at 37°C and/or adjusted chemically. Three levels of tHb were prepared by separating the red cells from the plasma and recombining appropriately. For each run, three replicates of each level were run on four 800 systems.

Table E-44 through Table E-46 summarize the results of the 800 CO-ox module recovery and precision testing.

Table E-44. 800 CO-ox Module Recovery and Precision with Total Hemoglobin of 5–8 g/dL and Oxyhemoglobin > 80%

Analyte	Mode	n	Mean Reference	Mean Difference from Reference	WRSD*
tHb	Capillary	72	6.64	–0.19	0.30
	Syringe	66	6.53	–0.27	0.11
FO_2Hb	Capillary	72	91.96	1.16	0.45

(Continued)

Analyte	Mode	n	Mean Reference	Mean Difference from Reference	WRSD*
	Syringe	66	92.18	0.90	0.39
*F*COHb	Capillary	72	4.23	–0.43	0.33
	Syringe	66	4.24	–0.45	0.12
*F*MetHb	Capillary	72	3.81	–0.95	0.68
	Syringe	66	3.58	–0.67	0.39
*F*HHb	Capillary	72	0.00	0.23	0.08
	Syringe	66	0.00	0.22	0.05

* WRSD = within-run standard deviation

Table E-45. 800 CO-ox Module Recovery and Precision with Total Hemoglobin of 10–16 g/dL and Oxyhemoglobin > 80%

Analyte	Mode	n	Mean Reference	Mean Difference from Reference	WRSD*
tHb	Capillary	68	15.18	–0.36	0.35
	Syringe	66	15.00	–0.31	0.11
FO_2Hb	Capillary	68	92.31	–0.09	0.25
	Syringe	66	92.27	–0.23	0.29
*F*COHb	Capillary	68	4.52	0.24	0.45
	Syringe	66	4.02	0.19	0.19
*F*MetHb	Capillary	68	3.17	–0.44	0.25
	Syringe	66	3.71	–0.76	0.20
*F*HHb	Capillary	68	0.00	0.29	0.08
	Syringe	66	0.00	0.34	0.08

* WRSD = within-run standard deviation

Table E-46. 800 CO-ox Module Recovery and Precision with Total Hemoglobin of 18–22 g/dL and Oxyhemoglobin > 80%

Analyte	*Mode*	*n*	*Mean Reference*	*Mean Difference from Reference*	*WRSD**
tHb	Capillary	72	21.04	0.21	0.21
	Syringe	68	20.72	0.19	0.22
FO_2Hb	Capillary	72	90.03	–0.73	0.24
	Syringe	68	92.31	–1.21	0.64
*F*COHb	Capillary	72	6.56	0.53	0.16
	Syringe	68	4.48	0.95	0.72
*F*MetHb	Capillary	72	3.41	–0.08	0.21
	Syringe	68	3.21	–0.01	0.20
*F*HHb	Capillary	72	0.00	0.27	0.11
	Syringe	68	0.00	0.28	0.16

* WRSD = within-run standard deviation

Appendix F: Printed Reports

This appendix contains examples of the patient sample reports that you can print on the roll printer, the line printer, and the 800 series compatible ticket printer.

The examples display all parameters, patient sample data fields, temperature corrected values, entered values, and CO-oximeter values for the 800 series systems. Some of the reports display reference ranges. The report you print will look different if the system you are using measures different parameters or if all data entry fields are not filled in.

Roll Printer Reports

This section contains examples of the patient sample reports that you can print on the 800 system roll printer. The examples include all possible parameters, patient sample data fields, temperature corrected values, entered values, and CO-oximeter values for the 800 system. The examples include the following reports:

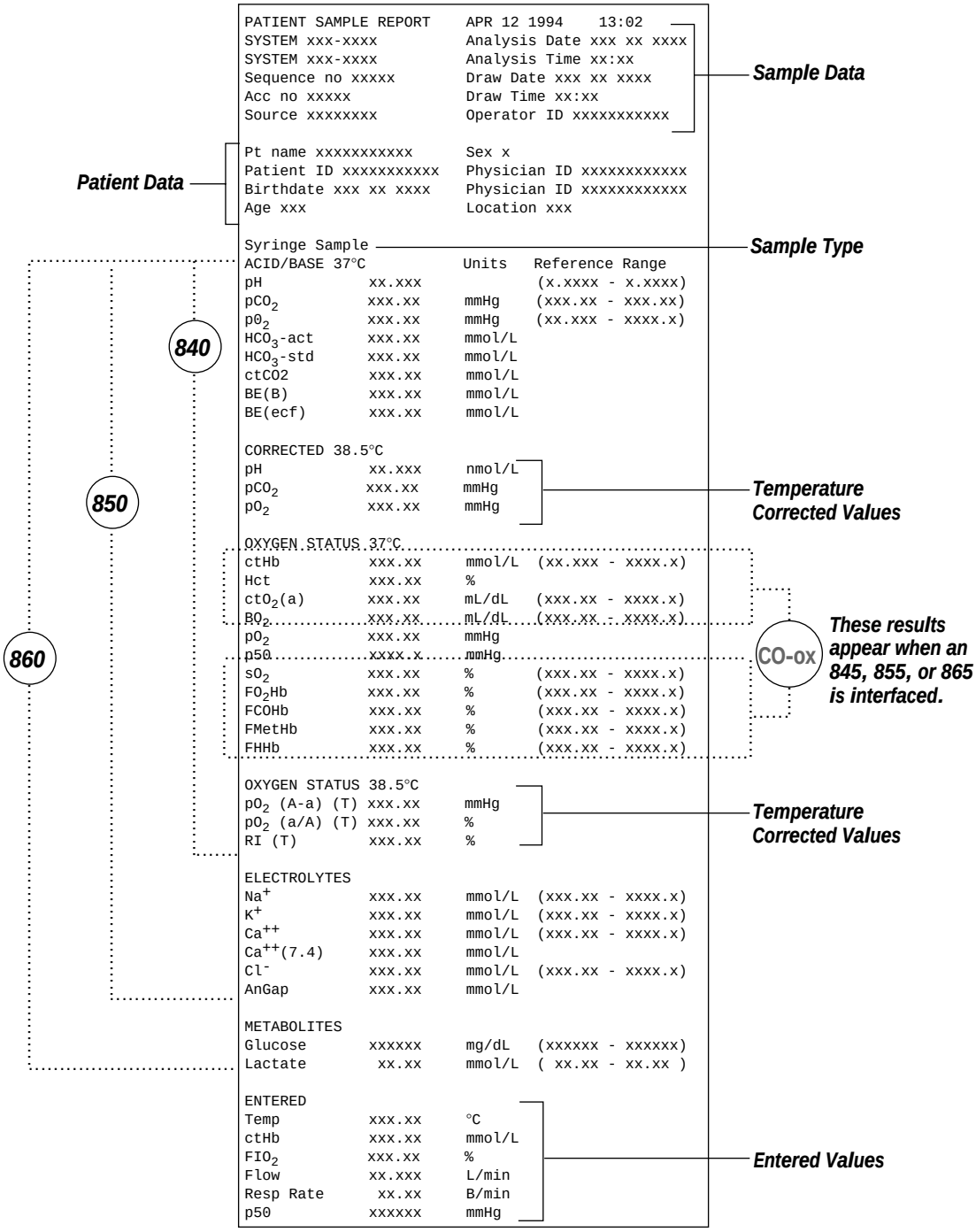
- Roll Printer Report A
- Roll Printer Report B
- Roll Printer Report C
- Roll Printer Report D
- Roll Printer Report E

Refer to *Defining the Printer Report Format* in Section 5 for information about how to select the roll printer report you want to print.

Roll Printer Report A

Roll Printer Report A is the default patient sample report. It displays reference ranges and it lists temperature corrected values separately. Figure F-1 shows an example of Roll Printer Report A.

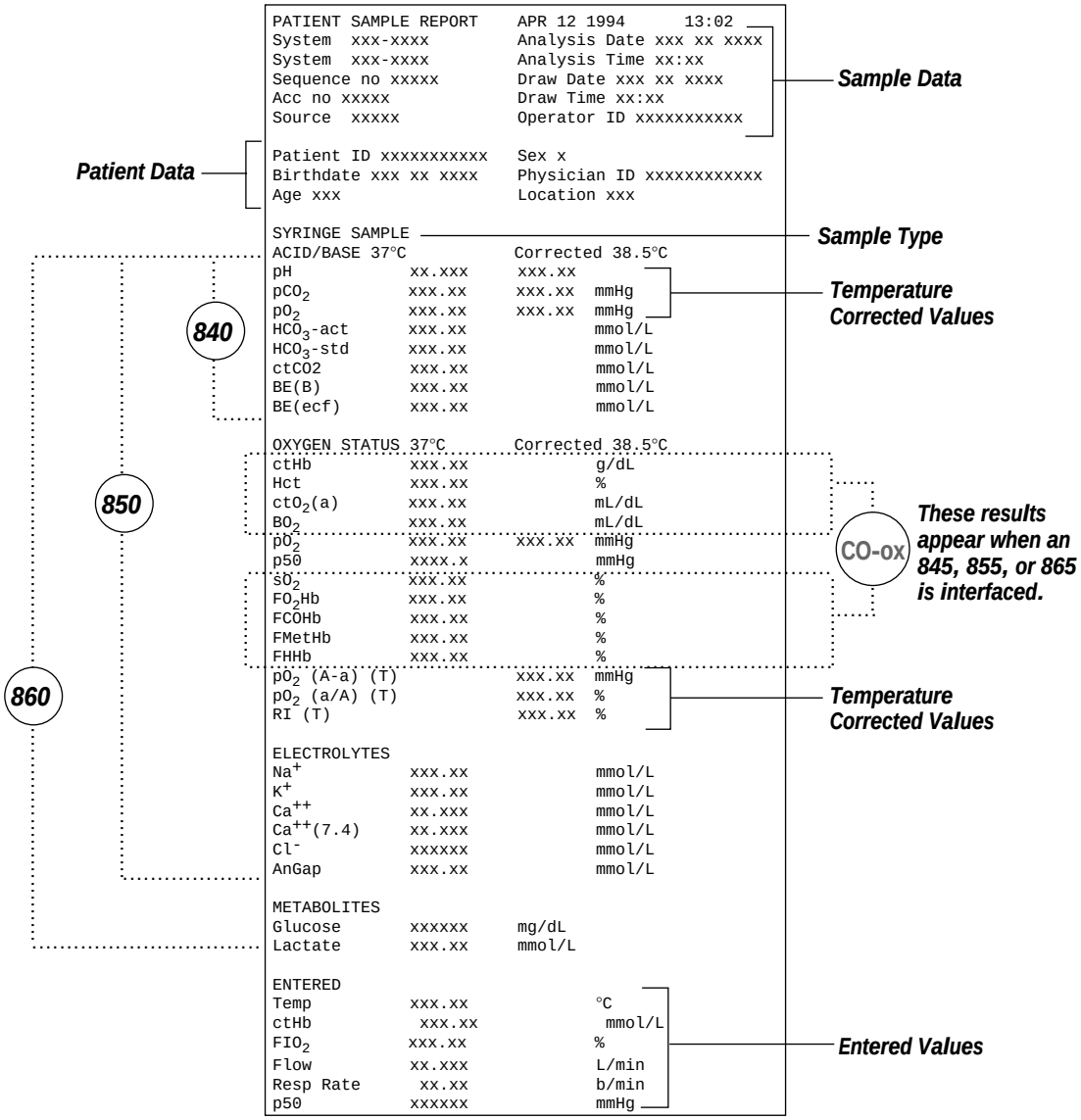
Figure F-1. Roll Printer Report A



Roll Printer Report B

Roll Printer Report B displays temperature corrected values next to the original values, and it does not display reference ranges. Figure F-2 shows an example of Roll Printer Report B.

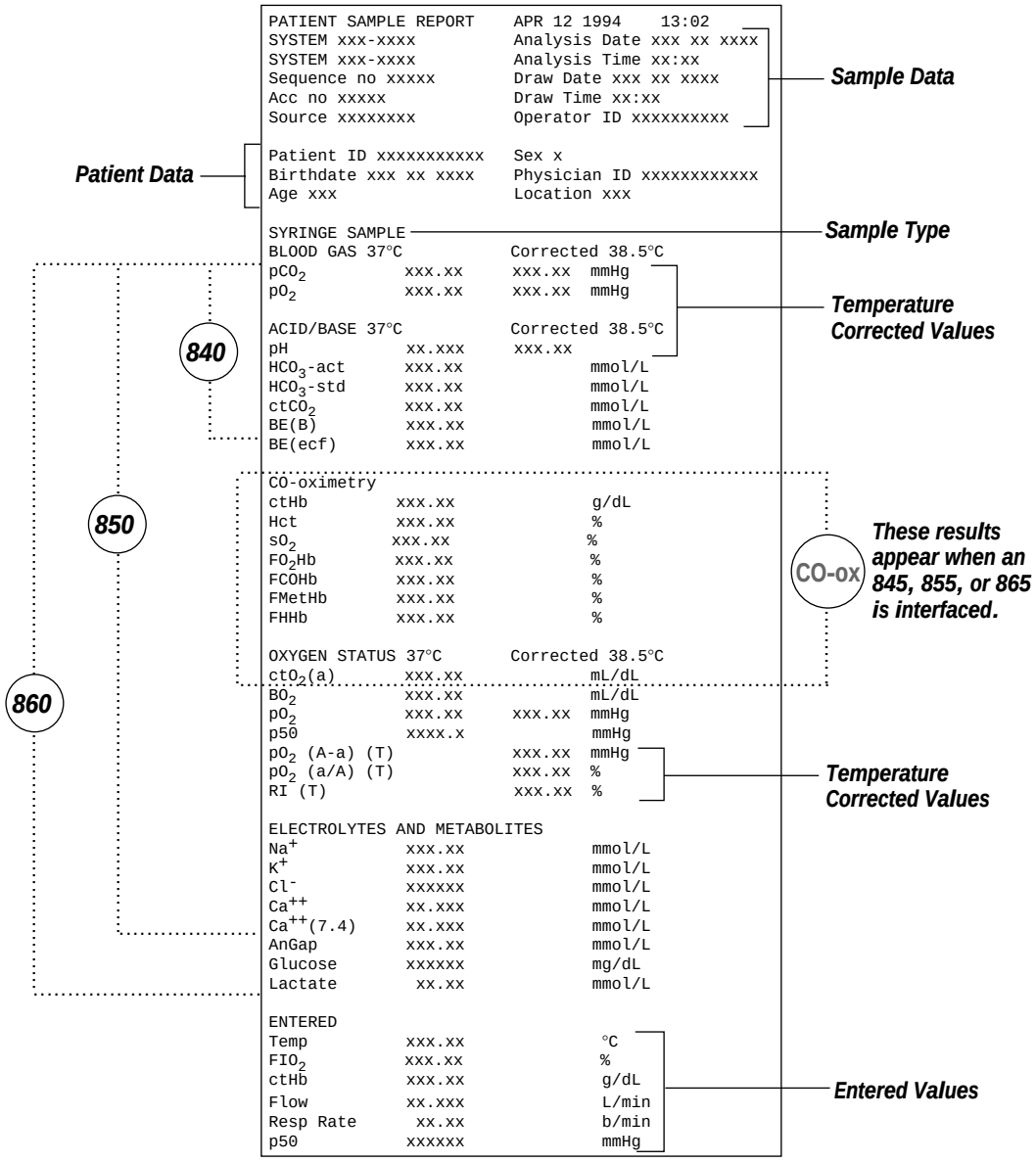
Figure F-2. Roll Printer Report B



Roll Printer Report C

Roll Printer Report C is similar to Roll Printer Report B, except that it lists blood gas and CO-oximeter values separately. Figure F-3 shows an example of Roll Printer Report C.

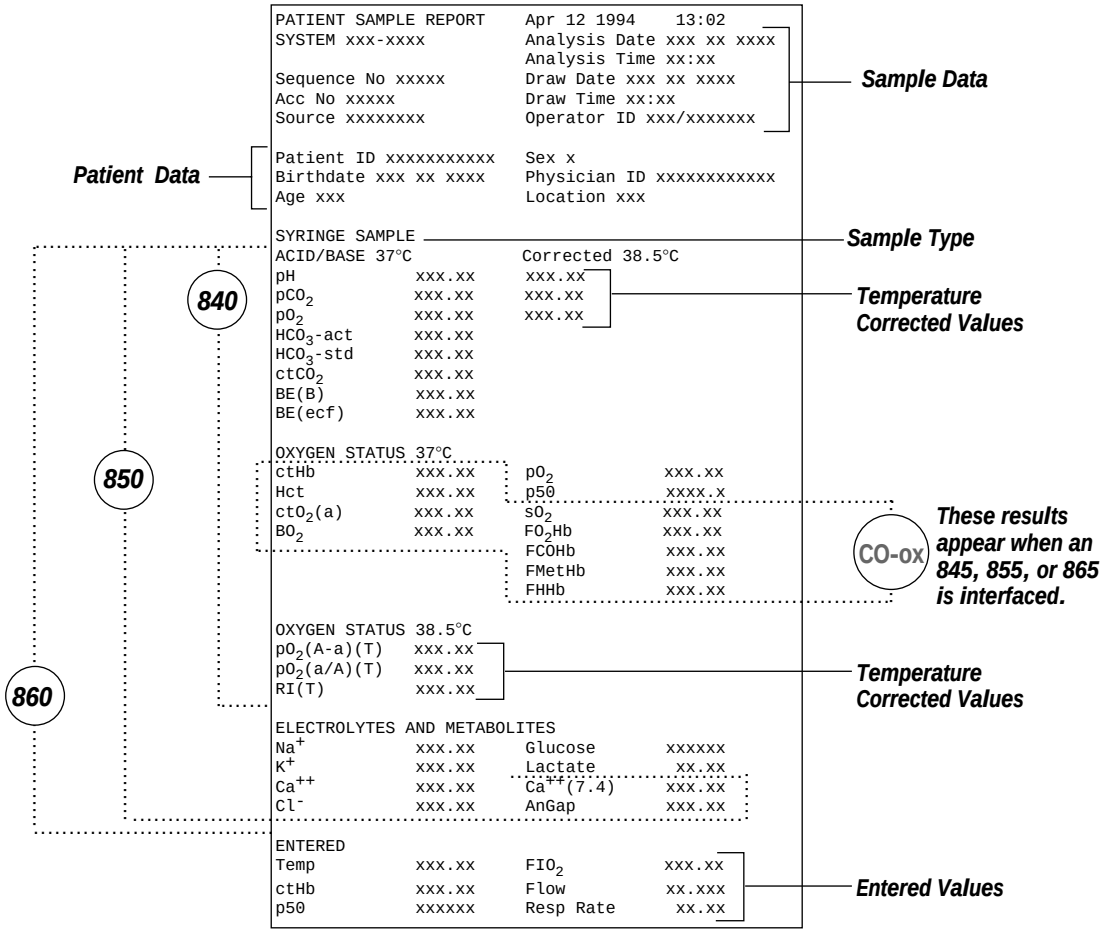
Figure F-3. Roll Printer Report C



Roll Printer Report D

Roll Printer Report D provides a four-column layout of parameters. Figure F-4 shows an example of Roll Printer Report D.

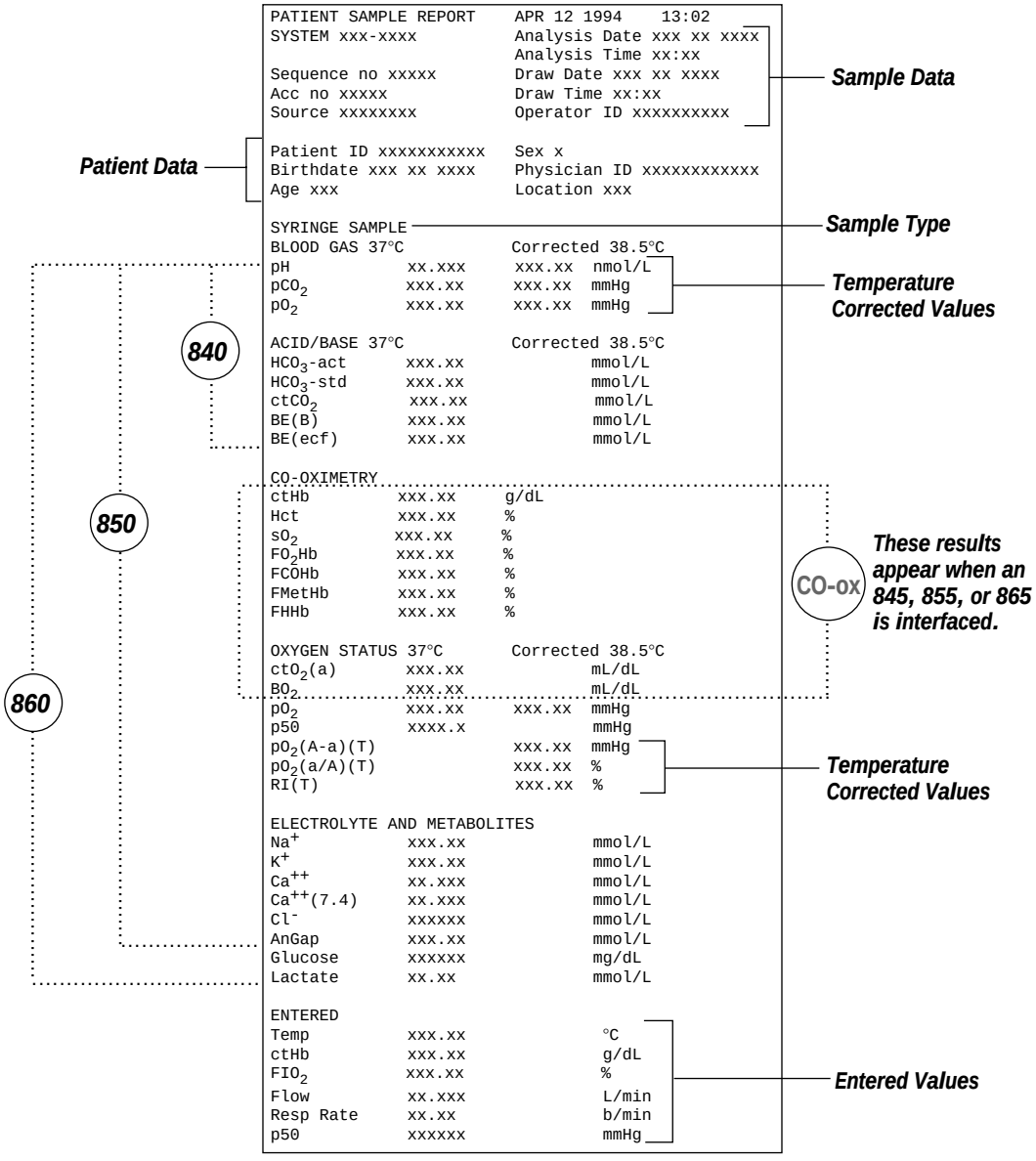
Figure F-4. Roll Printer Report D



Roll Printer Report E

Roll Printer Report E is similar to Report C, except that it includes the pH value with the blood gas values. Figure F-5 shows a sample of Roll Printer Report E.

Figure F-5. Roll Printer Report E



Line Printer Reports

This section contains examples of the patient sample reports that you can print on a line printer. The examples include all possible parameters, patient sample data fields, temperature corrected values, entered values, and CO-oximeter values for 800 systems. The examples include the following reports:

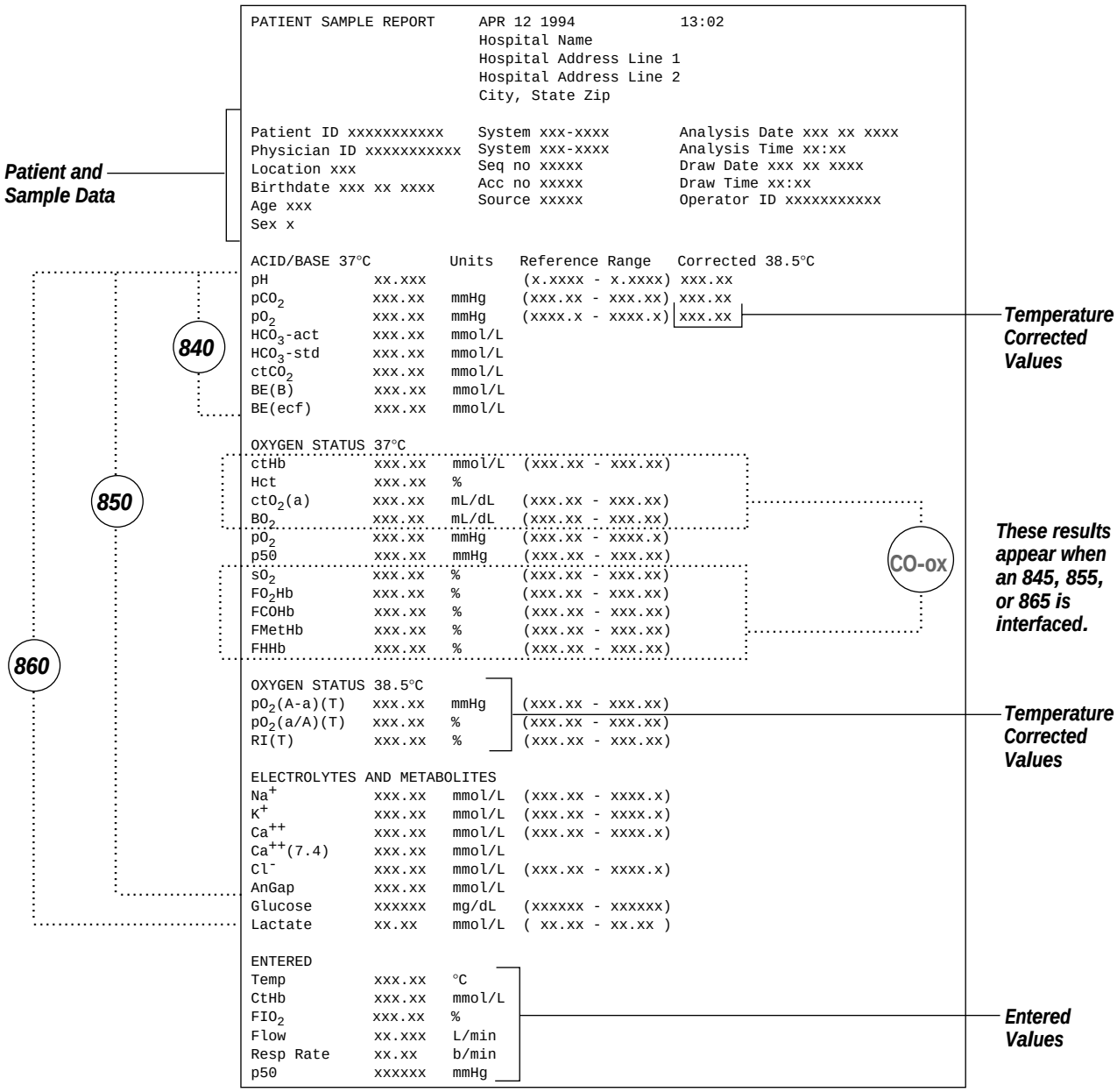
- Line Printer Report A
- Line Printer Report B
- Line Printer Report C

Refer to *Defining the Printer Report Format* in Section 5 for information about how to select the line printer report you want to print.

Line Printer Report A

Line Printer Report A is the default line printer report. It includes the CO-oximeter values with the oxygen status values. Figure F-6 shows an example of Line Printer Report A.

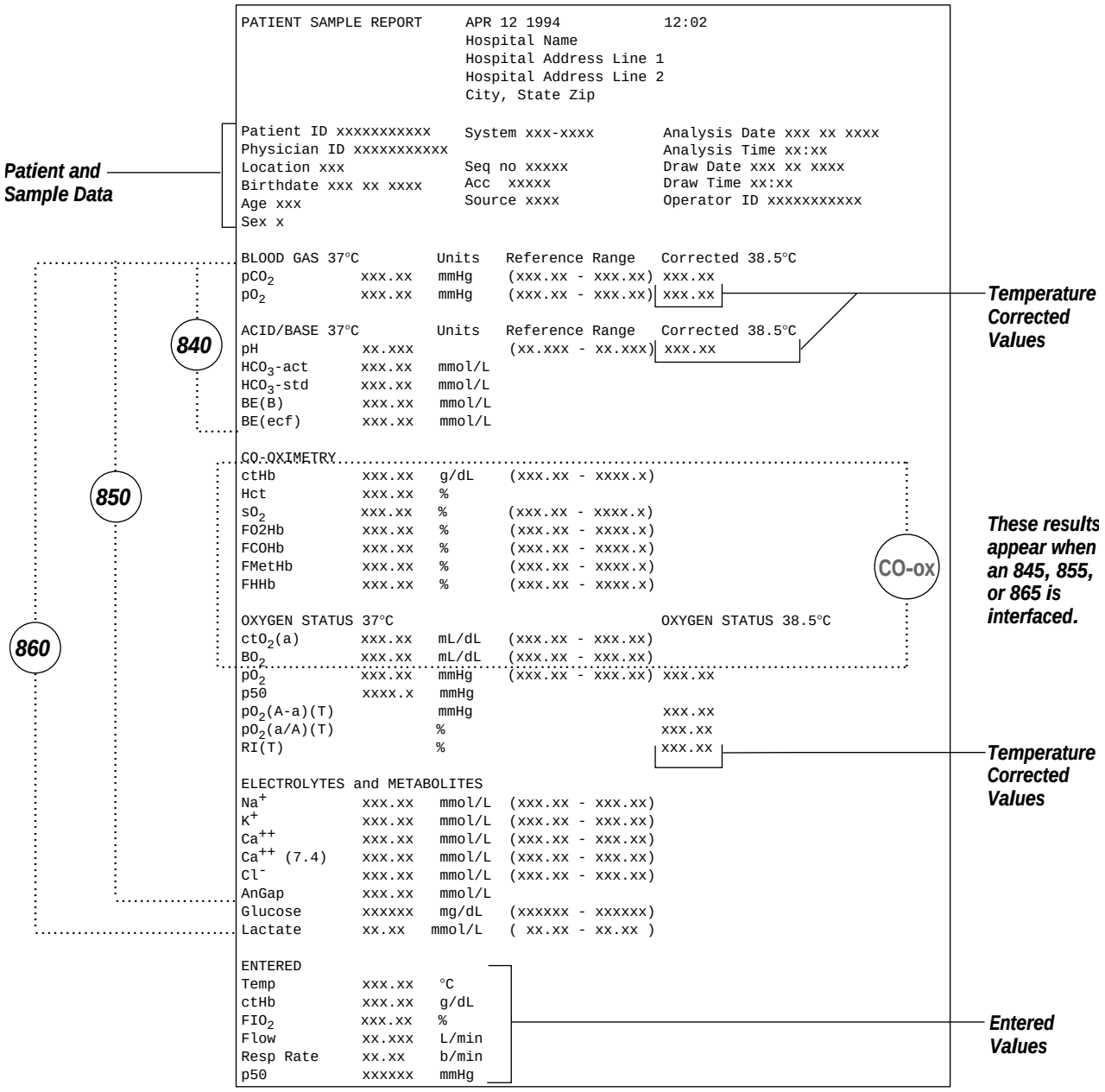
Figure F-6. Line Printer Report A



Line Printer Report B

Line Printer Report B lists blood gas and CO-oximetry values separately. Figure F-7 shows an example of Line Printer Report B.

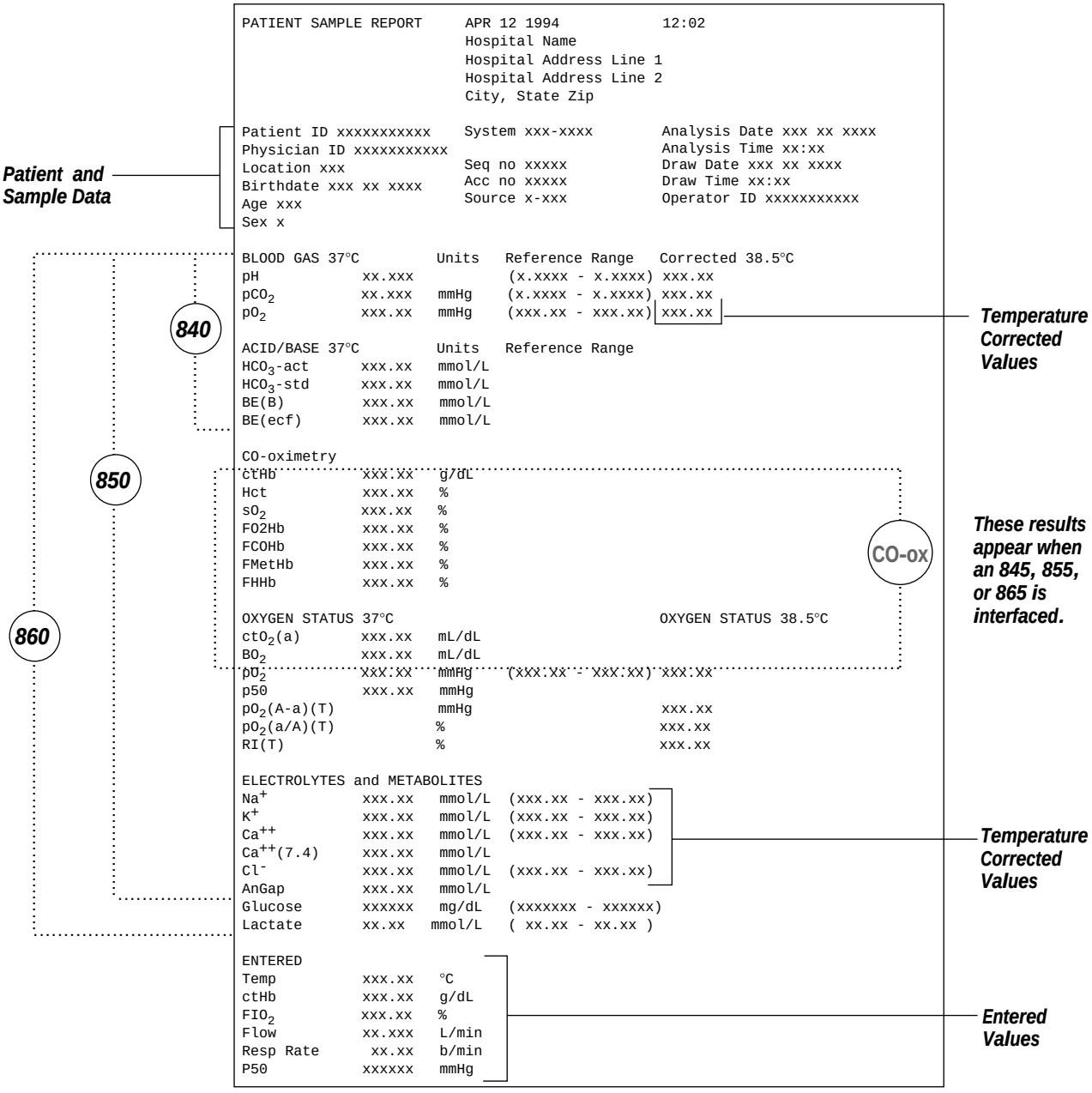
Figure F-7. Line Printer Report B



Line Printer Report C

Line Printer Report C is similar to Report B, except that it includes the pH value with the blood gas values. Figure F-8 shows an example of Line Printer Report C.

Figure F-8. Line Printer Report C



Ticket Printer Report

This section contains an example of the patient sample report you can generate from the 800 series compatible ticket printer.

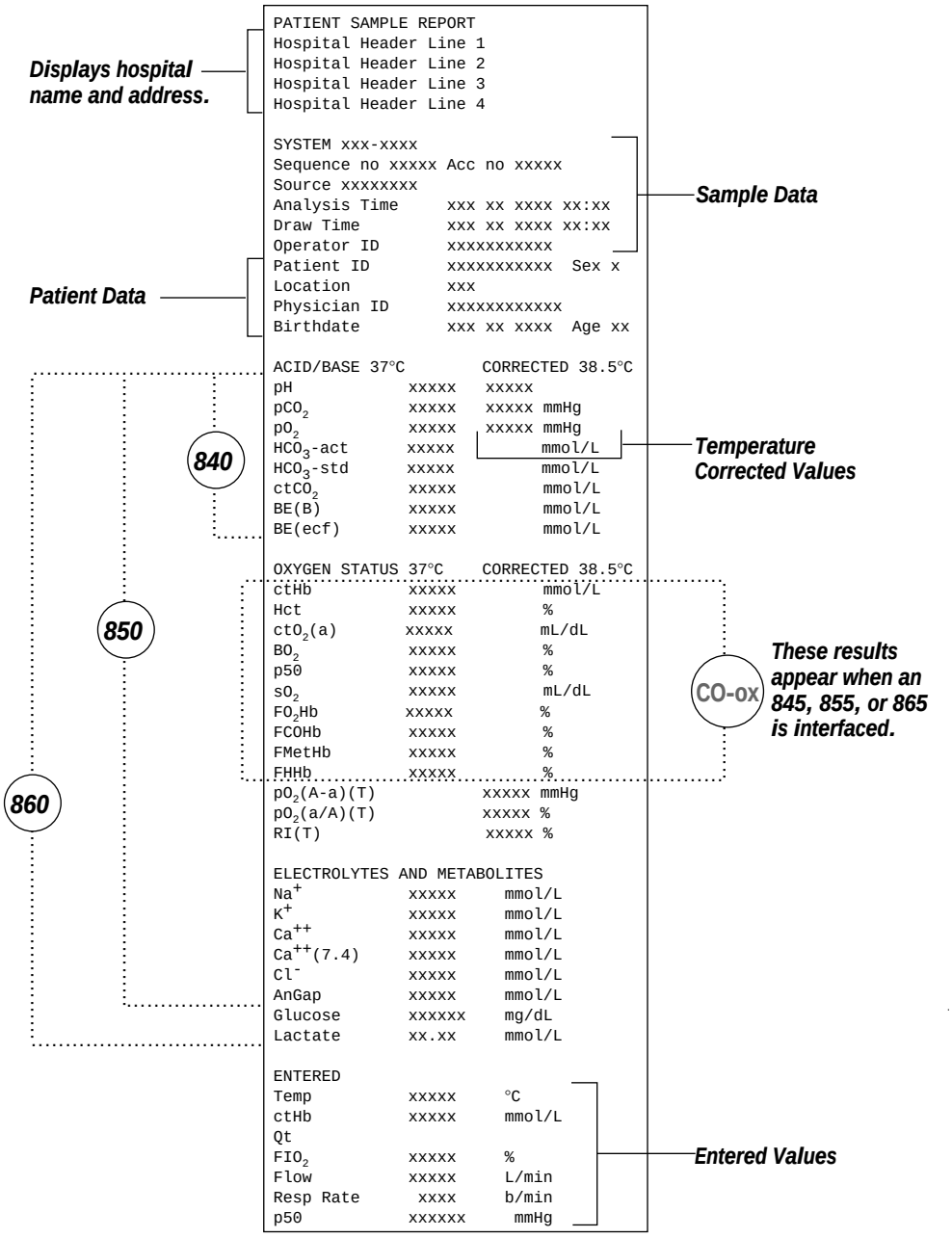
The ticket printer report displays only 45 lines of data. You can define the data that appears on the report by selecting the parameters and data entry fields in Setup. Do not use the optional hospital header lines and delete some parameters in Setup to limit the report length to 45 lines.

NOTE: If you do not complete a field on the Patient Information Screen, the field does not appear on the ticket printer.

Refer to *Defining the Printer Report Format* in Section 5 for information about how to select the ticket printer report. Refer to *Defining the Patient Information Form* and *Selecting Parameters for Analysis* in Section 5 for more information about turning off data entry fields.

Figure F-9 shows an example of a ticket printer report that contains all parameters, patient sample data fields, CO-oximeter values, and entered parameters in the correct order of appearance. This example displays more than 45 lines of data.

Figure F-9. Ticket Printer Report with all Fields



Appendix G: Correlation Adjustment

The 800 system provides a setup option, *Defining Correlation Coefficients*, that you can use to adjust the slope and intercept values to correlate results from an 800 system with results from another analyzer or methodology.

Before changing these values, you must simultaneously analyze a range of samples on the 800 system and on a reference analyzer. A properly conducted regression analysis will provide the appropriate correction equation slope and offset values.

NOTE: Changing the correlation coefficients affects the recovery of calibration verification materials and proficiency survey materials when analyzed as patient samples. Consult your proficiency survey administrator for detailed instructions on reporting adjusted results.

Use the following procedure to determine the slope and offset values for the correction equation.

Menu Code

5 ***8***

1. Access the Correlation Coefficients screen from the Menu screen:
   a. Select **5 Operating Setup**, and press **Enter**.
   b. Select **8 Correlation**, and press **Enter**.
   The Correlation Coefficients screen appears.
2. Ensure that the slope values are set to 1.000 and the offset value is set to 0.00 for each analyte that will be correlated to the reference methodology.
3. Press **Exit Menu** to return to the Ready screen.
4. Use a large sample population (minimum of 100 samples spanning the entire analytical and reporting range) to obtain a random distribution of sample values.

   NOTE: Failure to include a significant number of results at the extremes of the concentration ranges will compromise the quality of the correlation.
5. Analyze each of the samples concurrently on both the 800 system and the reference analyzer. Do not allow more than 3 minutes between paired analyses. The data collection should take place over several days to allow the inclusion of normal analytical variability for both methods. It is recommended that samples be run in duplicate on both the 800 system and the reference analyzer
6. Remove any statistical outliers beyond ±3SD.

7. Perform a linear regression analysis of the duplicate pairs of results
   a. The regression should be performed by a computer capable of calculating the regression by the Deming method. The debiased slope and offset provided by this method is the recommended process for method comparison.
   b. Compute the correction equation by setting the 800 system as the X (independent variable) and the reference analyzer as the Y (dependent variable).

   The calculation provides the equation y = mx +b where m is the slope and b is the offset.

   NOTE: The calculation must be made in the manner described. The calculation of a correction equation is the mathematical inverse of the traditional correlation equation. Failure to calculate the regression as described will cause the results to move further from the reference analyzer.

   A less acceptable alternative is to perform the linear regression on a calculator or computer that cannot use the Deming method. Set the 800 system as the X variable and the reference analyzer as the Y variable.

8. Enter the slope and offset correlation values for the 800 system. Refer to *Defining Correlation Coefficients* in Section 5.

Appendix H: Installation

Your 800 system should be installed by an authorized Bayer Diagnostics representative. Use the following procedure to install your 800 system yourself only if you are located in a region where Bayer Diagnostics Field Service Representatives do not perform installation. For detailed information about the software, refer to *Learning About the System* in Section 1 and *Operating the System* in Section 2.

Select a location for your system. Place the 800 system in a location that is not exposed to direct sunlight. Refer to Table H-1 for the system specifications.

Table H-1. System Specifications

Property	*Specification*
ambient operating temperature	15 – 32°C
ambient operating relative humidity	5 – 85%, non-condensing
power rating	400VA (maximum)
voltage requirements	100V/120V (85V to 132V) 50/60Hz 220V/240V (170V to 264V) 50/60Hz
ambient operating barometric pressure	400 – 825 mmHg (53.0 – 110.0 kPa)
system dimensions	height 50.8 cm (20 inches) width 55.9 cm (22 inches) depth 50.8 cm (20 inches) weight 29.5 kg (65 lbs)

Materials required:

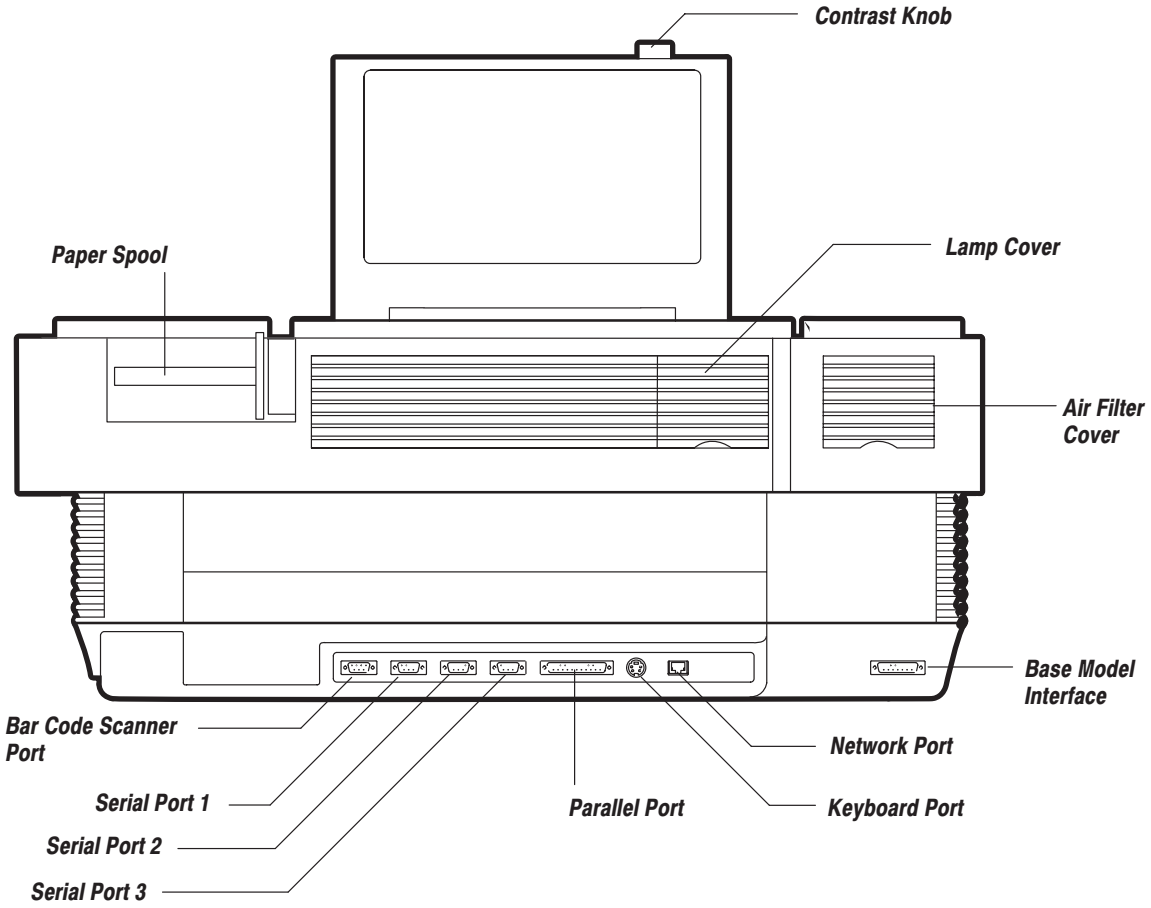
- Phillips screwdriver

860 ⚠ **CAUTION:** Do not remove the glucose or lactate biosensors from their packages during room temperature equilibration.

1. Remove the glucose and lactate biosensors from the refrigerator and allow them to equilibrate at room temperature (18 – 25°C) for at least 1 hour before use.

2. Inspect the packing case and report any damage to the shipper. Notify your Bayer Diagnostics representative at installation.
3. Cut the shipping straps and open the packing case.
4. Remove the installation tray and set it aside.
5. Carefully lift the packing case up and off of the system. If you anticipate relocating your system, do not discard the packing case.
6. Place the system on a level work surface, with the rear panel accessible.
7. Remove any tape and protective packing material from the system.
8. Unpack the installation tray and check the contents against the printed list included in the box.
9. Open the system:
   a. Turn the fasteners one-half turn to the left with a Phillips screwdriver.
   b. Lift the top of the system up and secure the hinges.
10. Inspect PC boards and cables:
    a. Remove the card cage cover.
    b. Ensure that the PC boards are seated properly.
    c. Ensure that all of the cables are connected.
11. Close the system:
    a. Release the hinges.
    b. Turn the fasteners one-half turn to the right with a Phillips screwdriver.
12. Install the optional bar code scanner:
    a. Remove the bar code scanner from the shipping carton.
    b. Connect the bar code scanner to the bar code scanner port on the rear panel as shown in Figure H-1.

Figure H-1. Rear View



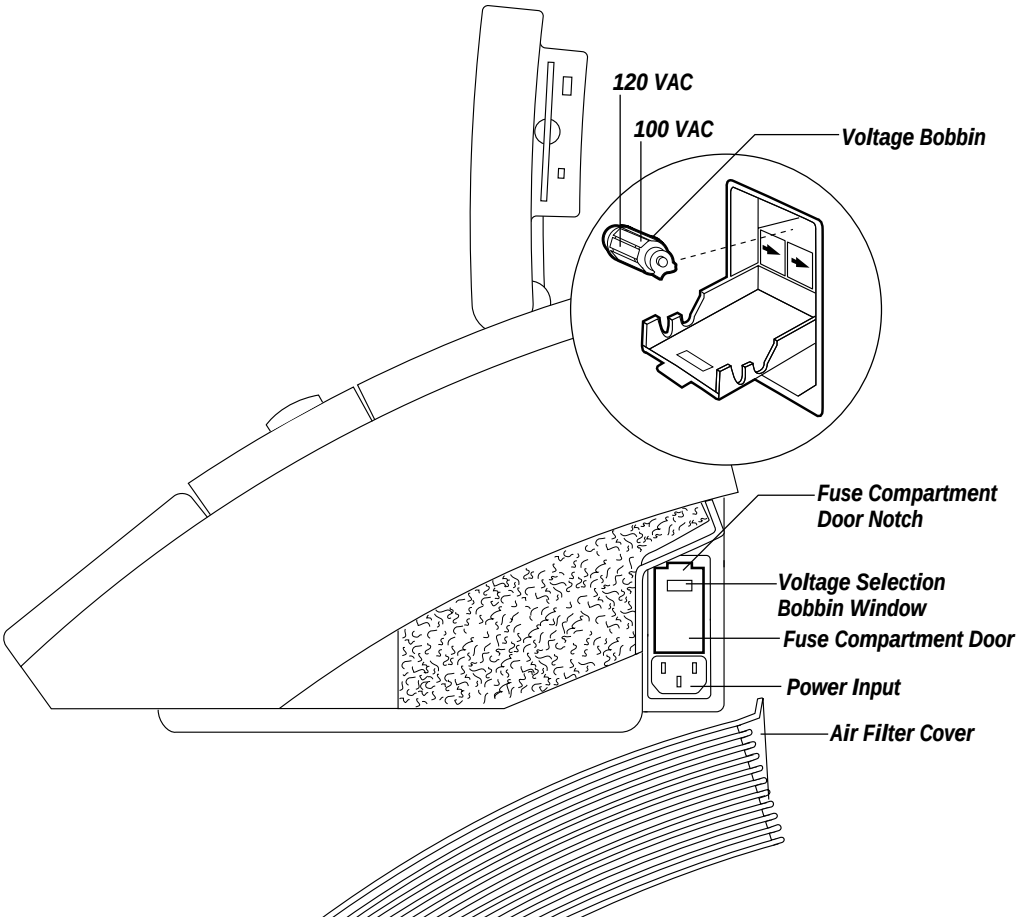
13. Rotate the system so that the right side panel faces you.
14. Install the fuses as required for your system

If . . .	*Then . . .*
your system has no voltage bobbin, it uses a universal power supply suitable for 100V to 240V	gently pry open the fuse compartment door using a small, flat–blade screwdriver and continue with step e.
your system has a voltage bobbin	continue with step a.

    a. Take the voltage bobbin from the customizing box and the fuse kit from the installation kit.
    b. Gently pry the fuse compartment door open using a small, flat-blade screwdriver.
    c. Select the operating voltage.

       Rotate the voltage bobbin so that the correct voltage faces you.
    d. Install the voltage bobbin as shown in Figure H-2.

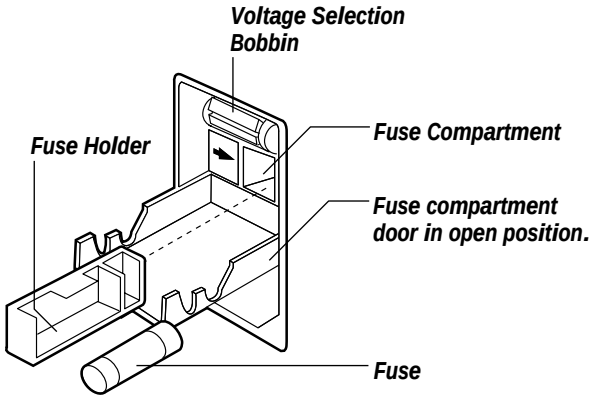
Figure H-2. Installing the Voltage Bobbin



e. Check the system fuses.

f. Pull one of the fuse holders out of the fuse compartment, as shown in Figure H-3.

Figure H-3. Installing the System Fuses



Refer to the table below to identify the correct fuses for the voltage you use.

Voltage	Fuse Rating	Fuse Type
100/120V	4A Slo Blo	5 x 20 mm
220/240V	2A Slo Blo	5 x 20 mm

g. Install the fuses as shown in Figure H-3.

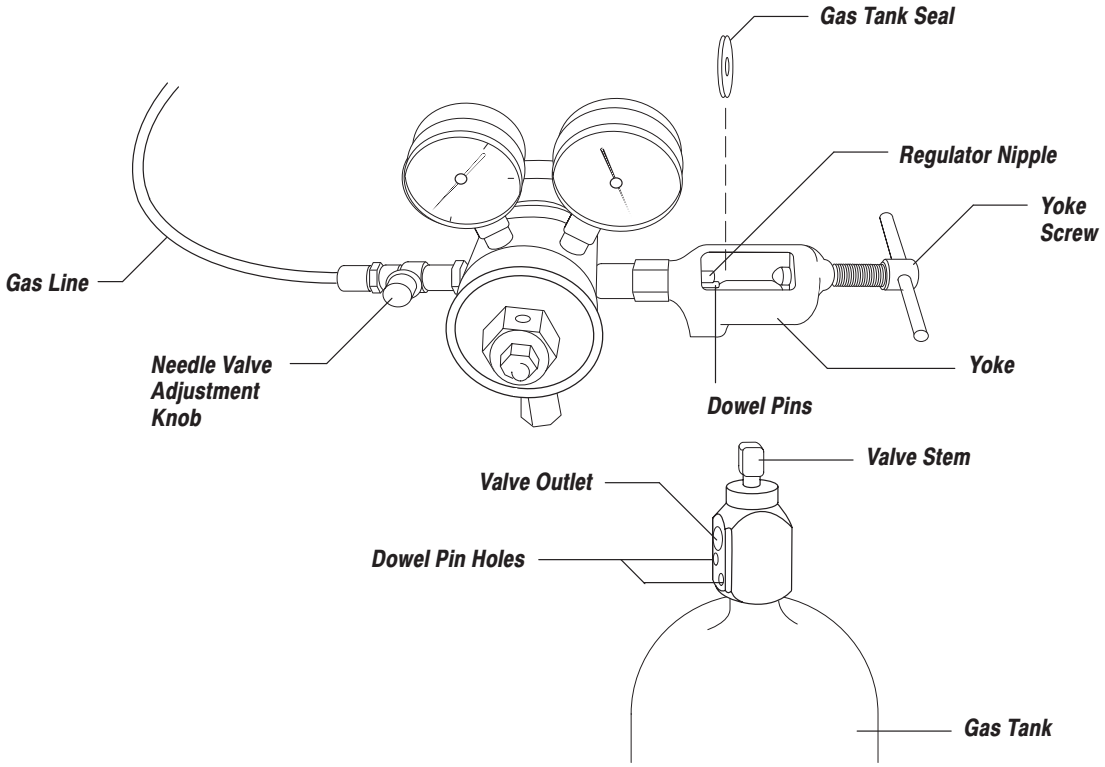
h. Slide the fuse holder(s) back into the fuse compartment. Make sure that the arrow on the end of the holder points to your right, as indicated by the arrows printed inside the compartment.

i. Close the fuse compartment door and make sure that the required voltage is visible through the compartment window.

WARNING Do not connect the power cord to the AC wall outlet.

15. Insert the power cord into the power input connector on the right side panel.
16. Rotate the system so that the front panel faces you.
17. Adjust the Display assembly:
    a. Remove the packing material from the hinges.
    b. Lift the display assembly up.
18. Remove the front cover of the system.
19. Install the calibration gas tanks as shown in Figure H-4 and Table H-2:
    a. Remove the gas connector cover.
    b. Unpack the calibration gas kit from its packing case.
    c. Place the gas tanks (cal gas and slope gas) into their final positions and secure them.
    d. Peel the white plastic protective wrapping from the valve assembly of each tank.
    e. Install the gas tank seals on the regulators.

Figure H-4. Installing the Gas Tank Regulator

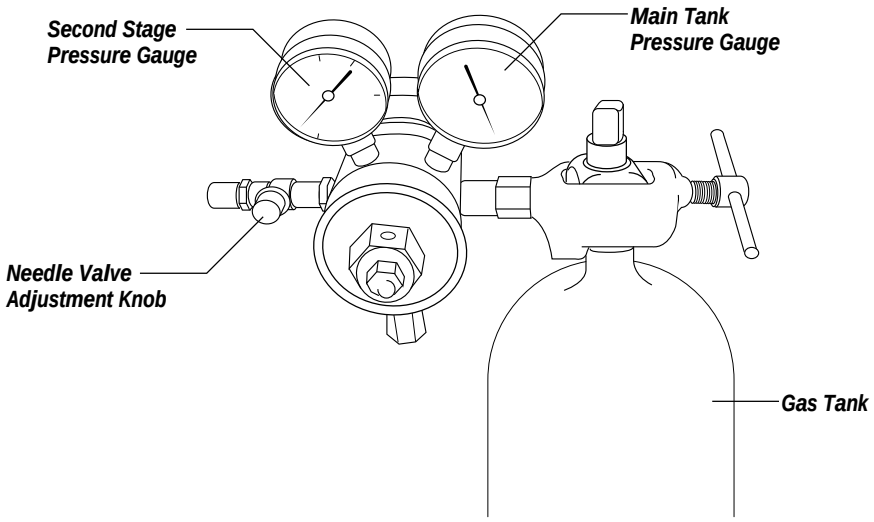


f. Attach the gas regulators to the gas tanks with the regulator nipple engaging the opening in the tank valve.

g. Attach and tighten the yoke screws firmly.

h. Attach and tighten the tubing adapter fittings into each needle valve. Ensure that the needle valve is fully open.

Table H-2. Gas Tank with Regulator Installed



i. Connect one end of a length of black tubing to the regulator fitting on the slope gas tank (10% CO_2).

j. Connect the tubing attached to the slope gas tank to the slope connector on the reagent manifold.

k. Connect one end of a length of black tubing to the regulator fitting on the cal gas tank (5% CO_2, 12% O_2).

l. Connect the tubing attached to the cal gas tank to the cal connector on the reagent manifold.

m. Direct the tubing in the tubing guide under the system either to the left, to the right, or behind the system.

n. To prevent restrictions in the tubing and uneven gas flow, secure the slope and cal gas tubing so that the tubing does not cross under the system.

o. Reinstall the gas connector cover.

20. Initiate gas flow:

a. Ensure that the tanks are connected correctly. The slope gas tank contains 10% CO_2 with the balance N_2. The cal gas tank contains 5% CO_2 and 12% O_2 with the balance N_2.

b. Slowly open each main tank valve using the wrench from the calibration gas kit until the regulator pressure gauge indicator stops rising (approximately 3/4 of a turn; average psi is 2200).

c. Open the valve one more turn.

d. Listen for any gas leakage. Check by using soapy water and look for bubbles.

e. Verify that each regulator outlet gauge indicates 3 – 5 psi.

21. Install the reagents:

    NOTE: Do not tighten or remove the bottle cap or attempt to mix the contents of one bottle with another. The bottle caps are adjusted to ensure proper reagent flow.

    a. Remove the plugs from the reagent bottle caps.

    b. Record the installation date in the space provided on the reagent labels.

    c. Slide the bottles into position in the reagent compartment. The reagents must be placed as follows from left to right on the reagent manifold:

7.3 Cal	6.8 Slope	Wash/Zero	C1/C2

860

7.3 Cal	6.8 Slope	Wash/Zero	C1/C2	Cal G/L

22. Prepare the waste bottle:

    a. Remove the waste bottle.

    b. Remove the protective packaging from the waste detector.

    c. Replace the waste bottle and ensure it is seated properly.

23. Prepare the reference sensor:

    a. Partially fill the internal reference electrode compartment with 4M KCl solution, and tap to remove bubbles.

    b. Continue to fill the internal reference sensor compartment until the 4M KCl fill solution flows into the reservoir.

    c. Use the hex tool to remove the internal reference electrode from its container. Insert the internal reference electrode into the reference electrode compartment. Screw it into place using the hex tool. Do not cross thread the internal sensor into the compartment. Tap the sensor to remove bubbles.

    d. Remove the reservoir cap with the hex tool.

    e. Fill the reservoir to the fill line with 4M KCl fill solution.

    f. Put the reservoir cap back into position. Hand tighten the reservoir cap.

    NOTE: Do not overtighten. Overtightening can deform the gasket and cause leakage.

    g. Wipe any excess KCl solution from the exterior of the reference sensor with a lint-free tissue.

    h. Tap the sensor with your knuckle to remove bubbles.

24. Install the reference sensor:
    a. Open the measurement module door by pushing up on the latches located on the lower corners to release the door, and then lifting the door up.
    b. Push the spring-loaded latch to the right.
    c. Verify that the O-rings are in place on both sides of the sensor.
    d. Verify that the O-ring is in place on the left side of the spring-loaded latch.
    e. Align the top of the reference sensor with the sensor contact.
    f. Snap the body of the sensor down into place.
    g. Ensure that the sensor O-rings are in place.

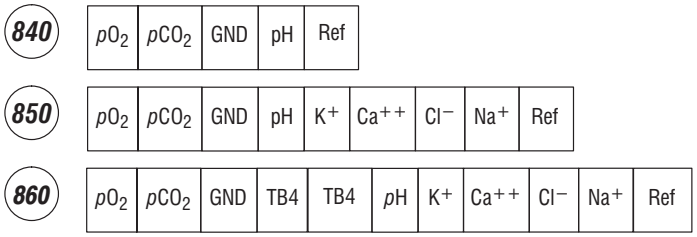
850 860

25. Fill the Cl^- sensor:
    a. Grasp the tab on the blank sensor. Pull it up and out of the measurement module.
    b. Remove the Cl^- sensor from its package.
    c. Unscrew the internal electrode and carefully set it aside on a lint-free tissue.
    d. Rinse the sensor body with 3 drops of the Na^+, K^+, Cl^-, Ca^{++} fill solution and empty.
    e. Slowly add the fill solution until the sensor is almost full.
    f. Screw the internal electrode into place.
    g. Tap the sensor with your knuckle to remove bubbles.
    h. Wipe the sensor with a dry lint-free tissue.
    i. Ensure that the O-ring is in place on the left side of the sensor.
    j. Align the top of the sensor with the sensor contact.
    k. Snap the body of the sensor down into place.
26. Connect the power cord to the AC wall outlet.

    The system begins a power-up sequence. Wait for the Not Ready screen to appear.
27. Verify that the sensors are almost full of fill solution. If any sensor is not filled correctly, follow the procedure *Filling the Measurement Sensors* in Section 3, using the appropriate fill solution.

    NOTE: The Na^+ sensor should be full. The pH, K^+, Cl^-, and Ca^{++} sensors should be almost full.
28. Verify that each O-ring is correctly positioned.
29. Press down the tab on the spring-loaded latch to release it.

30. Verify that the sensors are installed in the following order:



31. Close the measurement module door.
32. Install the reagent pump tubing:
    a. Disconnect the right side of the tubing from right positions 1 and 2.
    b. Remove the tubing cuff from the right side of the platen.
    c. Place the tubing over the top of the roller cage.
    d. Hold the right tubing cuff, turn the roller cage clockwise, and work the new tubing between the platen and roller cage. Do not stretch the tubing.

    NOTE: It is normal for the pump tubing to fit tightly.

    e. Place the right tubing cuff under the right side of the platen.
    f. Connect the right end of the large tubing to position 1.
    g. Connect the right end of the small tubing to position 2.
33. Install the sample pump and waste pump tubing:
    a. Disconnect the right side of the sample pump tubing.
    b. Place the tubing over the top of the roller cage.
    c. Hold the right tubing cuff, rotate the roller cage clockwise, and gently work the new tubing between the platen and roller cage. Do not stretch the tubing.

    NOTE: It is normal for the pump tubing to fit tightly.

    d. Place the right tubing cuff under the right side of the platen.
    e. Connect the right tubing to the manifold at position 4.
    f. Repeat steps a through d for the waste pump tubing.
    g. Connect the right tubing to the manifold at position 5.
34. Install the printer paper:
    a. Lift the printer cover up.
    b. Place the paper roll in the cavity with the paper unrolling from the bottom.
    c. Lift the printer lever up.
    d. Push the paper under the platen until it comes out of the other side in front.

e. Pull the paper from under the platen and push it through the slot in the printer cover.

f. Push the printer lever down.

35. Close the printer cover:

a. Pull up the paper spool.

b. Insert the paper into the paper slot on the spool and turn three or four rotations. Press **Paper Advance** if there is not enough paper.

c. Push down the spool.

36. Access the Menu screen and set up your system.

Refer to *System Administration* in Section 5 for more information about setting up the system.

Menu Code
2 ***3***

37. Initiate a prime sequence from the Menu screen to remove bubbles from the reagent lines:

a. Select **2 Maintenance** and press **Enter**.

b. Select **3 Prime** and press **Enter**.

c. Select **All** and press **Enter**.

d. Press **Done**.

e. Watch the movement of wash solution to verify that the wash reagent flows through the system during the wash sequence that automatically follows the prime sequence.

38. Verify the gas flow rates for cal gas and slope gas:

a. Access the Valves Test from the Menu screen.

b. Select **Cal Gas** and press **Start Test**.

c. Insert an aspiration adapter into the sample port.

d. Immerse the open end of the aspiration adapter into a small container of reagent water.

e. Press **Start Test**.

f. Verify that a steady stream of bubbles flows into the water.

g. Press **Stop Test**.

h. Verify that the bubbles stop flowing.

i. Repeat steps b through h for slope gas.

j. Remove the aspiration adapter.

k. Press **Exit Test**.

Menu Code
3 ***2***

39. Access the Temperature test from the Menu screen:

a. Select **3 Troubleshooting** and press **Enter**.

b. Select **2 Temperature** and press **Enter**.

c. Check the screen to verify that the sample temperature is 37.00 ± 0.15°C.

NOTE: If the temperature is outside of the range, verify that the power has been on for at least 30 minutes.

Menu Code 1 8

40. Access the Barometer screen from the Menu screen:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **8 Barometer** and press **Enter**.

    The Barometer Calibration screen appears.

41. Compare the displayed atmospheric pressure to the laboratory's barometer reading.

If . . .	***Then . . .***
the displayed atmospheric pressure is correct	press **Done**. The Ready screen appears.
the displayed atmospheric pressure is incorrect	a. Type the correct atmospheric pressure, and press **Enter**. b. Press **Done** to save the new atmospheric pressure and return to the Ready screen. c. Perform a gas two-point calibration.

42. Condition the sensors.

    Refer to *Conditioning the Sensors* in Section 3.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

860

43. Install the glucose and lactate biosensors:
    a. Remove test/blank sensors (TB4).
    b. Remove the lactate and glucose biosensors from the foil package.
    c. Align the contacts on the biosensors with the contacts in the measurement module.
    d. Snap the body of the biosensors down into place. The contacts must be flush with the sensors.
    e. Press the tab on the spring-loaded latch down to release the latch.
44. Verify that the sensors are installed in the following order:

860

pO_2	pCO_2	GND	Glu	Lac	pH	K^+	Ca^{++}	Cl^-	Na^+	Ref

45. Perform three two-point calibrations to start hydrating the glucose and lactate biosensors as soon as possible.
46. Allow the glucose and lactate biosensors to equilibrate for at least 30 minutes.
47. Verify that the system temperature is within the acceptable range.

48. Verify sensor performance by completing two successful two-point calibrations.

    The Ready screen appears when the calibration finishes.

49. Analyze QC material and verify acceptable results.

50. Replace the front cover.

Attaching the 800 CO-oximeter Module to the 800 Base Model

BIOHAZARD: Refer to Appendix A for recommended precautions when working with biohazardous materials.

The 800 series CO-oximeter (CO-ox) module must be installed by an authorized Bayer Diagnostics Representative. Unauthorized use of these procedures can void the warranty or service contract.

For detailed information about the software, refer to *Learning About the System* in Section 1 and *Operating the System* in Section 2 of the operator's manual.

Select a location for the new system configuration where it is not exposed to direct sunlight. Refer to Table H-3 for system specifications.

Table H-3. System Specifications

Property	*Specification*
ambient operating temperature	15 – 32°C
ambient operating relative humidity	5 – 85%, non-condensing
power rating	400VA (maximum)
power requirements from the 800 base model:	100V (±) 10% 50/60 Hz 120V –15 to +10% 50/60 Hz 220V (±) 10% 50/60 Hz 240V (±) 10% 50/60 Hz

(Continued)

Property	Specification
ambient operating barometric pressure	400 – 825 mmHg (53.0 – 110.0 kPa)
system dimensions	height 30.3 cm (11.94 inches) when installed 47.8 cm (18.81 inches) width 17.35 cm (6.83 inches) when installed 70.3 cm (27.66 inches) depth 50.8 cm(20.0 inches) weight 7.9 kg (17.5 lbs) when installed 36.5 kg (82 lbs)

Tools and Supplies

- flat-blade screwdriver #2 [15.24 cm (6 inches) minimum shank length]
- Phillips screwdriver #2 [15.24 cm (6 inches) minimum shank length]
- pliers

Unpacking the CO-ox Module

1. Inspect the packing case and report any damage to the shipper.
2. Prepare a level work surface for the 800 CO-ox module.
3. Open the box:
   - Cut the tape along the edge of the top flap.
   - Open the flaps.
4. Remove the product inserts:
   - Unpacking Instructions
   - Ship Damage Instructions
   - Contact Bayer Diagnostics Representative Insert
5. Remove the printer cover and the 800 instrument rear label. Set them aside.

   The new printer cover replaces the printer cover on the base model. The 800 instrument rear label is placed over the model number information on the 800 base model.

   NOTE: Do not cut the black straps surrounding the module. The straps assist in lifting the module out of the packing case.
6. Use the black straps to carefully lift the CO-ox module from the packing case and to place the module upright on the work surface.
7. Cut the black straps.

8. Carefully remove the foam end caps from the module.
9. Remove the plastic bag surrounding the module.
10. Remove any tape used to secure parts during shipment.

Shutting Down the System

If you are installing the CO-ox module to an operational 800 series system, perform the following procedure to shut down the system.

Menu Code
7 3

1. Shut down the system from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **3 Shutdown** and press **Enter**.
      The Shutdown screen appears.
2. Press **Yes**.
   A message appears on the screen and on the roll printer, directing you to wait before you disconnect the power.

CAUTION: Do not unplug the system until the following message appears on the screen:

```
...synching disks... done
```

This is an operating system message indicating that the system has successfully completed the shutdown procedures. Unplugging the system before this message appears can damage the system.

3. When you see the operating system message, disconnect the power cord from the power supply.

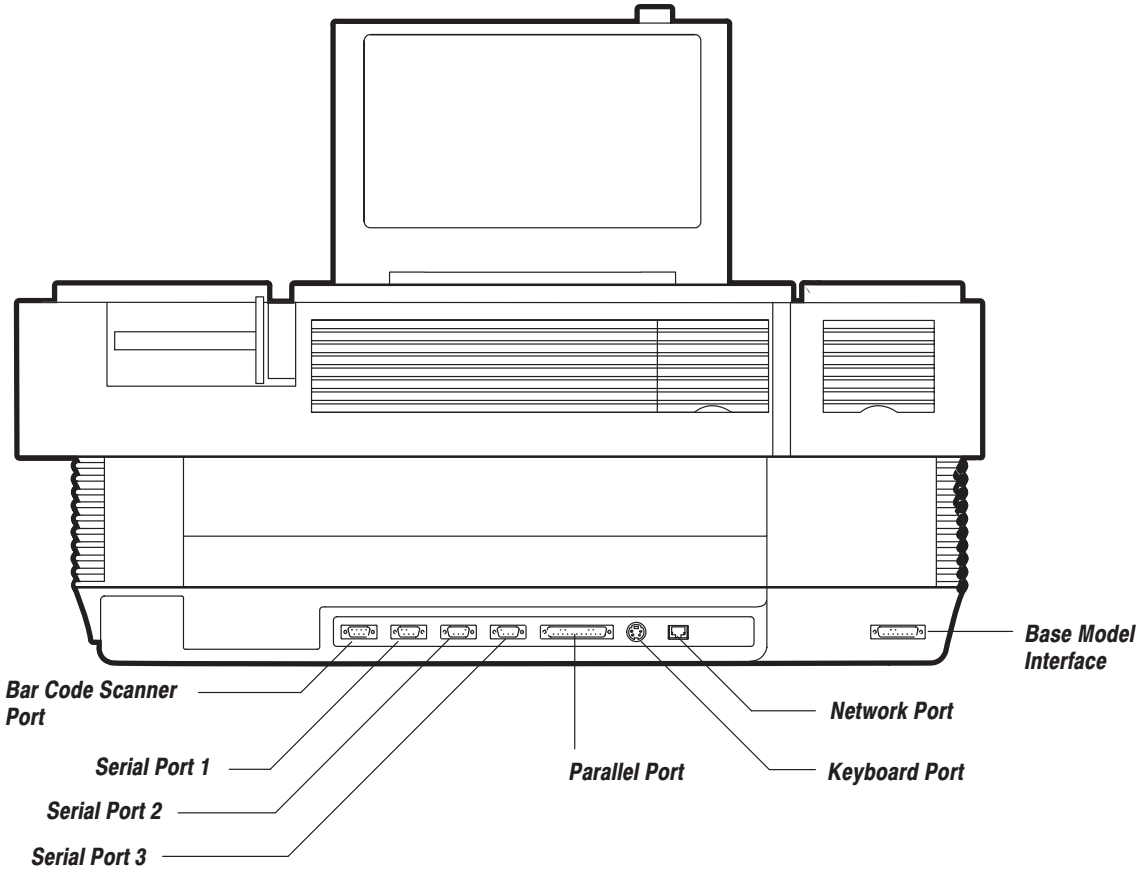
Preparing the 800 Base Model

This procedure refers to right and left as you look at the rear of system.

1. Disconnect the power cord from the 800 base model.

   NOTE: Note the port location of each cable to ensure cables are reconnected correctly.
2. Disconnect the cables from the ports at the rear of the 800 base model. Refer to Figure H-5.

Figure H-5. The Rear Panels



3. Open the 800 base model, secure the spring locks, access and remove the right side panel by loosening the captive screws mounted on the interior floor of the chassis. Do not remove the screws. Retain the side panel.

   NOTE: Slide the base model to the edge of the work surface to access the front plug.

4. Remove the two plugs mounted to the right side wall of the base model hydraulic wall:

   a. Push on the plug stems that protrude from the interior of the hydraulic wall.

   b. Remove the plugs and retain.

Preparing the 800 CO-ox Module

1. Lift the hydraulic wall of the CO-ox module to access the power cable.
2. From inside the CO-ox chassis push the connector end of the cable through the slot and gently pull the cable through.

Installing the 800 CO-ox Module to the 800 Base Model

This procedure refers to right and left as you are looking at the rear of system.

NOTE: Placing a piece of paper under the CO-ox module will allow for easier movement on the work surface.

1. Move the CO-ox module close to the right side of the 800 base model.
2. Ensure that the CO-ox module hydraulic wall is open and slide the hydraulic wall into position.
3. Install the CO-ox power cable:
   a. Insert the CO-ox module power cable through the access hole in the side of the 800 base model.
   b. Gently pull the cable through the access hole while pushing the CO-ox module as close to the 800 base model as possible.
   c. Connect the CO-ox module power cable to J38 on the 800 base model Backplane board.
4. Install the side panel from the base model to the CO-ox module.
5. Close the 800 base model, but do not tighten the locking screws.
6. Lift the side of the 800 base model up slightly to ensure that the lip of the CO-ox module is seated in the groove located under the chassis shelf of the 800 base model.

   Ensure that the two bosses on the CO-ox module are seated in the two receptacles of the base model and that the screws are aligned with the bosses. Do not tighten the screws.
7. Move the CO-ox module hydraulic wall laterally along its hinge pin until the sides of both units touch.

   NOTE: The two alignment bosses on the left side of the CO-ox module hydraulic wall must be seated properly in the hydraulic wall receptacles of the 800 base model.

CAUTION: Do not crimp or pinch tubing between the hydraulic walls.

8. Secure the hydraulic walls together:

   NOTE: Install the top rear screw first. You may need to remove the filter if it prevents access to the top (upper rear) through hole. Be careful not to cut the optics cable when securing the bottom (lower front) screw.
   a. Ensure that the rear walls of both chassis are properly aligned.
   b. Ensure that the captive screws are not engaged in the threaded portion of the CO-ox hydraulic wall.
   c. Insert a screwdriver into the access holes on the CO-ox module hydraulic wall and tighten the screws to secure the hydraulic walls together.

9. Open the hydraulic walls and lock the counterbalance hinges.
10. Tighten the two screws in the alignment bosses on the CO-ox module chassis to the chassis receptacles of the 800 base model.
11. Install the two plugs retained from the 800 base model to the right side wall. Ensure that the new adhesive dots are in place.
12. Install the communications cable connectors between the CO-ox module and the 800 base model to the CO-ox communications ports shown in Figure H-5. Tighten the connector screws.
13. Ensure that the CO-ox module PC boards are firmly seated.
14. Ensure the the lamp is aligned correctly in the keyway and firmly seated in the housing retainer.
15. Apply the new instrument label over the existing instrument label.

Installing the Sample Connector to the Fluid Path

1. Access the preheater on the measurement module and disconnect the sample tubing.
2. Remove the sample connector:
   a. Remove the screw, located in the front of the preheater block, that attaches the sample tee adaptor and retain.
   b. Remove the sample tee adaptor.

      Ensure that the gasket around the tube is in place and does not slip off the end of the tube.

⚠ **CAUTION:** Overtightening the screw can damage the sample tee adaptor.

3. Invert the position of the sample connector and reinstall it to the preheater on the 800 base model so that two sample tubes are facing toward you.
4. Reinstall the sample tubing:

If you are installing a sample tee adaptor on . . .	*Then . . .*
an old style manifold	a. Remove the left manifold cap and place the CO-ox module sample tubing on the manifold so that it is flush against the flat. b. Replace the manifold cap being careful not to pinch the sample tubing.
a new style manifold	push the sample tubing into the recessed slot on top of the manifold.

NOTE: Ensure that the waste tubing is positioned through the hole on the CO-ox module fluid detector.

5. Connect the waste tubing to the 800 base model manifold.
6. Connect the sample tubing to the sample connector.

Installing the Printer Cover with Correct Model Number

This procedure refers to right and left as you look at the front of system.

1. Remove the printer paper.
2. Remove the old printer cover:
   a. Lift the cover and slide it to the right until the cover flange clears the pivot pin.
   b. When the left side of the cover is free of the pivot pin, pull the cover to the left to remove it from the printer.
3. Install the new printer cover:
   a. Slide the left tab over the pin on the spindle arm bracket while pushing the cover all the way to the left.
   b. Bend the tab on the cover or pivot it to allow the tab to slide over the pivot pin.

Removing the Tubing Tab from the 800 Base Model

1. Locate the groove on the left side of the base model front cover.
2. Using pliers, grasp the tubing tab inside the grooved area. Move and flex the tubing tab to weaken the joint until the tab breaks free from the cover.
3. Close the system:
   a. Tighten both locking screws on the base unit.
   b. Tighten the one locking screw on the CO-ox module.

Updating the System ID

This procedure is used by Bayer Diagnostics Service Representatives to change the system information that the 800 system uses to present information on the screen and in printed reports.

NOTE: A service password is required to access this setup function.

1. Reconnect all cables to the ports as shown in Figure H-5.

2. Plug the power cord into the AC power receptacle.

   At startup, the system proceeds through a series of initial tests and then displays Initializing in the banner. Any errors incurred during initialization are posted to the status log.

Menu Code 8 4

3. Access the Service Setup screen from the Menu screen:
   a. Select **8 Service Setup** and press **Enter**.
   b. Select **4 System ID** and press **Enter**.
4. Type the service password and press **OK**.
5. Select the system configuration(s) that you want and press **Enter**.
6. Enter the CO-ox module serial number and press **Enter.**
7. Press **Done**.
8. You can define another setup function or press **Exit Menu** to return to the Ready screen.
9. Access the Menu screen and set up your system.

   Refer to *System Administration* in Section 5 for more information about setting up the system.

Menu Code 1 2

10. Initiate a two-point calibration from the Menu screen:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **2 Two-point** and press **Enter**.
    c. Verify acceptable drift.

Menu Code 1 9

11. Initiate a tHb slope from the Menu screen:
    a. Select **1 Calibration** and press **Enter**.
    b. Select **9 tHb Slope** and press **Enter**.
    c. Verify acceptable drift.
12. Analyze QC material and verify acceptable results.

Relocating Your System

No special handling or preparation is required to relocate your system to another area in your laboratory. To store your 800 system for an extended period of time or to ship it to another location, perform the following procedures, or contact your Bayer Diagnostics Service Representative for assistance.

Materials required:

- 10% solution of household bleach
- sterile water
- reagent water

- lint-free tissue and swabs
- aspiration adapter
- test/blank sodium or pH sensor (TB2)
- glucose test/blank sensor (TB4)
- lactate test/blank sensor (TB4)
- reference test/blank sensor (TB5)
- valve wrench

BIOHAZARD: Refer to Appendix A for recommended precautions when working with biohazardous materials.

Cleaning the Sample Path with Bleach

860 

CAUTION: Exposure to bleach damages the glucose and lactate biosensor membranes. Replace the glucose and lactate biosensors with the test/blank (TB4) sensor before cleaning the sample path.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

1. Take the appropriate action.

If you have an . . .	*Then . . .*
840 or 850	Go to step 2.
860	a. Remove the glucose and lactate biosensors. b. Install the test/blank sensors. c. Go to step 2.

Menu Code
2 1

2. Deproteinize the sample path:
   a. Prepare the deproteinizer as directed on the package.
   b. Select **2 Maintenance** and press **Enter**.
   c. Select **1 Deproteinize** and press **Enter**.
   d. Invert the deproteinizer several times to mix.
   e. Insert an aspiration adapter into the sample port and insert the other end into the deproteinizer.
   f. Press **Analyze**.
   g. Remove the adaptor when prompted.
   h. Wait 5 minutes for the deproteinizing cycle to finish.

CAUTION: Prolonged exposure to the 10% bleach solution damages the reference sensor membrane. You must replace the reference sensor with a test/blank ref sensor (TB5) while you complete the cleaning procedure. Do not substitute a new reference sensor.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

3. Replace the reference sensor with a test/blank ref sensor (TB5):
   a. Remove the reference sensor from the measurement module and set it aside.
   b. Install a test/blank ref sensor (TB5) in the measurement module.

Menu Code ***2*** ***2***

4. Access the Condition screen from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **2 Condition** and press **Enter**.

WARNING Wear safety glasses, gloves, and a laboratory coat when handling the reagents.

5. To clean the sample pathway:
   a. Insert an aspiration adapter into the sample port and immerse the aspiration adapter in the 10% bleach solution.
   b. Press **Analyze**.
   c. Remove the aspiration adapter when prompted.
   d. Wait 5 minutes for cleaning to finish.

   NOTE: Press **Cancel** if you want to stop cleaning.

   e. Press **No**. The Menu screen appears.
6. Perform two additional wash sequences.

CAUTION: Do not remove or return the sensors to the measurement module without first discharging static buildup. Touch the inner surface of the module frame to discharge static buildup.

7. Replace the reference sensor:
   a. Remove the test/blank ref sensor (TB5) in the measurement module and set it aside.
   b. Install the reference sensor in the measurement module.

Cleaning Reagents from the Reagent Manifold

1. Remove all the reagent bottles from the system and perform a prime sequence.

Menu Code: 2 3

2. Access the Prime screen from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **3 Prime** and press **Enter**.
3. Select **All Reagents** and press **Enter**.
4. Press **Done**.
5. Press **Menu** to return to the Menu screen.
6. Press **No**.

Menu Code: 3 1 1

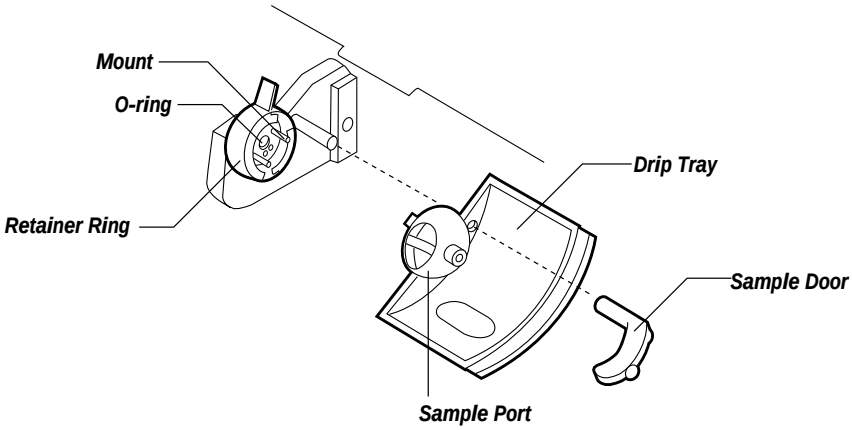
7. Access Fluidics Functions from the Menu screen:
   a. Select **3 Troubleshooting** and press **Enter**.
   b. Select **1 Fluidics System** and press **Enter**.
   c. Select **1 Fluidics Functions** and press **Enter**.
8. Select **C1/C2** and press **Enter**.
9. Press **Start Test**.
10. Press **Exit Test**.
11. Empty, rinse, and fill the four reagent bottles with reagent water.
12. Install the reagent bottles containing reagent water in place on the system.
13. Perform a Prime sequence as described in steps 2 through 6.
14. Perform an C1/C2 Fluidics Function Test as described sequence 7 through 10.
15. Remove the reagent bottles.
16. Air dry the pathways:
    a. Repeat steps 2 through 6 without the reagent bottles in place.
    b. Repeat steps 7 through 10 without the reagent bottles in place.

Cleaning the Sample Port

Menu Code: 2 7

1. Stop the system from the Menu screen:
   a. Select **2 Maintenance** and press **Enter**.
   b. Select **7 Stop System** and press **Enter**.
2. Grasp the sample door and pull it to the right as shown in Figure H-6.
3. Grasp the tab on the retainer ring and firmly pull the tab toward you to rotate the ring.

Figure H-6. Removing the Sample Port



4. Grasp the sample port and drip tray and pull it to the right to remove it.

   NOTE: The sample port and the drip tray are one piece.

   WARNING Wear safety glasses, gloves, and a laboratory coat when handling the reagents.

5. Clean any deposits on the sample port, the drip tray, and the mount with a lint-free swab moistened with a 10% solution of household bleach.
6. Rinse the sample port, the drip tray, and the mount with reagent water.

   NOTE: Ensure that the three O-rings are in place.

7. Reinstall the sample port, matching the tab on the sample port to the notch in the retainer ring.
8. Push the tab on the retainer ring away from you until it locks in place.
9. Reinstall the sample door, ensuring that it snaps in place.
10. Press **Continue**.
11. Press **No**.
12. Press **Home** to return to the Ready screen.

Cleaning the Exterior Surfaces

WARNING Wear safety glasses, gloves, and a laboratory coat when handling the reagents.

1. Using a 10% solution of household bleach, wipe all exterior surfaces including:
   - the sample entry components and the drip tray
   - the waste area

NOTE: Do not insert swabs into the sample port or spray anything into the measurement module.

2. Rinse the exterior surfaces with reagent water.
3. Clean spills around any of the roller cages, if required:
   a. Remove the roller cage as described in *Replacing a Roller Cage* in Section 3.
   b. Clean the roller cage and the roller cage shaft with a 10% solution of household bleach.
   c. Rinse with reagent water and dry thoroughly.
   d. Reinstall the roller cage.
4. Empty and discard the waste bottle. Clean waste outlets and waste outlet cover as described in *Emptying the Waste Bottle* in Section 3.
5. Remove the printer paper. Refer to *Replacing the Printer Paper* in Section 3.
6. Tape the printer cover in place.

Shutting Down the System

Menu Code
7 ***3***

1. Shut down the system from the Menu screen:
   a. Select **7 System Utilities** and press **Enter**.
   b. Select **3 Shutdown** and press **Enter**.
   c. Press **Yes**.

   The Shutdown screen appears.

CAUTION: Do not unplug the system until the following message appears on the screen:

```
...synching disks... done
```

This is an operating system message, indicating that the system has successfully completed the shutdown procedures. Unplugging the system before this message appears can damage the system.

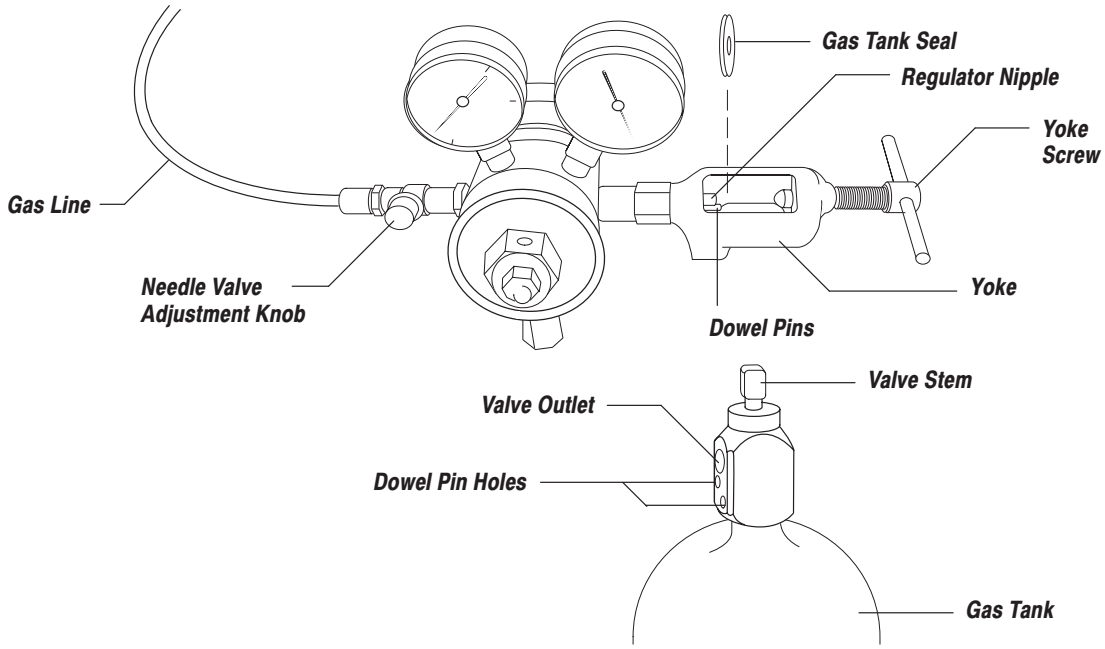
2. When you see the operating system message, you can disconnect the power cord from the power supply.

Removing the Gas Tanks

WARNING Compressed gas tanks require cautious handling. To prevent damage and possible personal injury, refer to *Replacing the Gas Tanks* in Section 3, for more detailed precautions.

1. Remove the gas tanks, as shown in Table H-4:

Table H-4. Removing the Gas Tank and Regulator



   a. Using a valve wrench, close each gas tank by turning the valve stem clockwise.
   b. Disconnect the gas regulators from the gas tanks by unscrewing the yoke screws.
   c. Verify that the gas tank seals are in place on the regulators.
   d. Remove the gas tanks to a well ventilated, open area.
   e. Position each valve outlet so that it is facing down, away from loose objects.

⚠ **CAUTION:** Avoid contact with the gas stream. Gas under pressure can cause bodily injury and property damage.

   f. Using the wrench, release the contents of the gas tanks by turning the valve stems counterclockwise.

g. When each gas tank is completely vented and the pressure is zero, label the container Empty, and dispose of the tanks according to your laboratory protocol.

   Bayer Diagnostics recommends that you remove the valve stems before disposal.

2. Pack the 800 system in the original shipping carton. If the original carton is no longer available, contact your Service Representative for a replacement shipping carton.

Appendix I: Operating Principles

The measurement technology used for the 800 critical blood analytes systems is based on electrochemical, biochemical and optical phenomena. Electrochemistry involves the measurement of current or voltage occurring in an electrochemical cell. The cell consists of two or more electrodes that interact with a chemical in solution and are connected to an electrical system.

Electrodes used for measurement in the 800 systems are called sensors. Sensors are responsible for direct measurement of a specific substance of interest in a sample. They must have the following characteristics: a molecular or ion-specific recognition mechanism, a transducer mechanism, and a signal processor system.

The molecular recognition mechanism gives a sensor its identity. Each sensor is designed to selectively measure the activity of a specific substance. Although many elements in a sample may interact with a sensor, the sensor is highly selective for one substance over others. The common recognition mechanism used in many 800 sensors is a membrane designed to be selective for a specific substance.

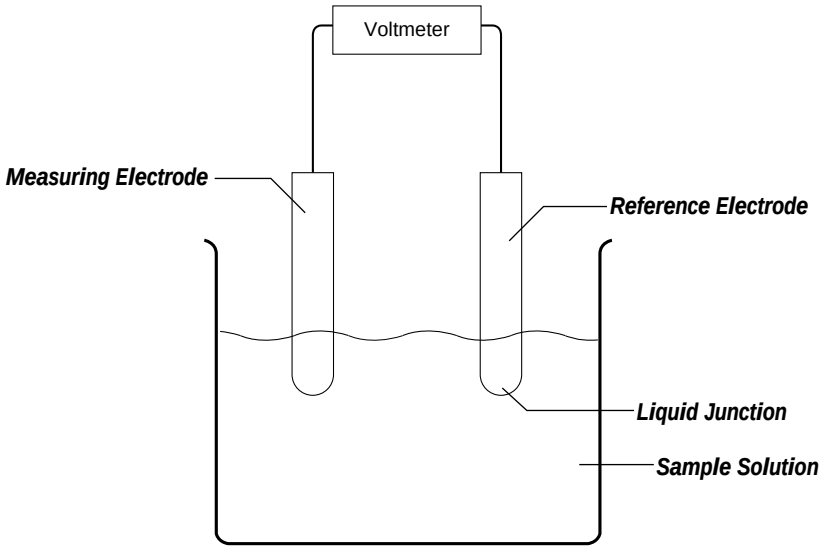
The transducer mechanism converts the potential generated by the molecular recognition mechanism to an electrical signal. In the 800 systems, this is accomplished through potentiometry or amperometry. Potentiometry is the technology that measures the difference in potential (voltage) between two electrodes (the molecular recognition mechanism) in a solution without applied current. Amperometry is a technique that involves applying voltage to the electrode and then measuring the current generated.

The signal processing system conditions the electronic signal from the sensor, through electronic smoothing and noise filtering. Then it converts the electronic signals into a concentration expressed in recognizable units of measurement.

Potentiometry

Potentiometry measures the voltage or potential generated between two electrodes in an electrochemical cell when no external current is applied; the cell is in a state of equilibrium. The electrochemical cell consists of two electrodes (a measuring or indicator electrode and a reference electrode), an electrolyte solution (sample solution), and a measuring device such as a voltmeter. The electrochemical cell is capable of measuring the concentration or activity of a substance in a solution. Refer to Figure I-1.

Figure I-1. Potentiometric Cell



Each electrode, which acts as a half-cell with a half-cell potential, contains an inner reference element immersed in an internal electrolyte solution. The measuring electrode is designed to respond to changes in the concentration of the specific analyte being measured in the sample solution. It develops a half-cell potential that is directly related to the concentration or activity of the specific analyte. The reference electrode provides a steady, unchanging potential to the cell. Both electrodes are connected to the measuring device. With the current in the cell at zero, the potential developed by the electrochemical cell is determined by calculating the difference in potential between the measuring electrode and the reference electrode.

$$E_{cell} = E_{meas} - (E_{ref} + E_{lj})$$

where

E_{cell} = electrochemical cell potential

E_{meas} = measuring electrode half-cell potential

E_{ref} = reference electrode half-cell potential

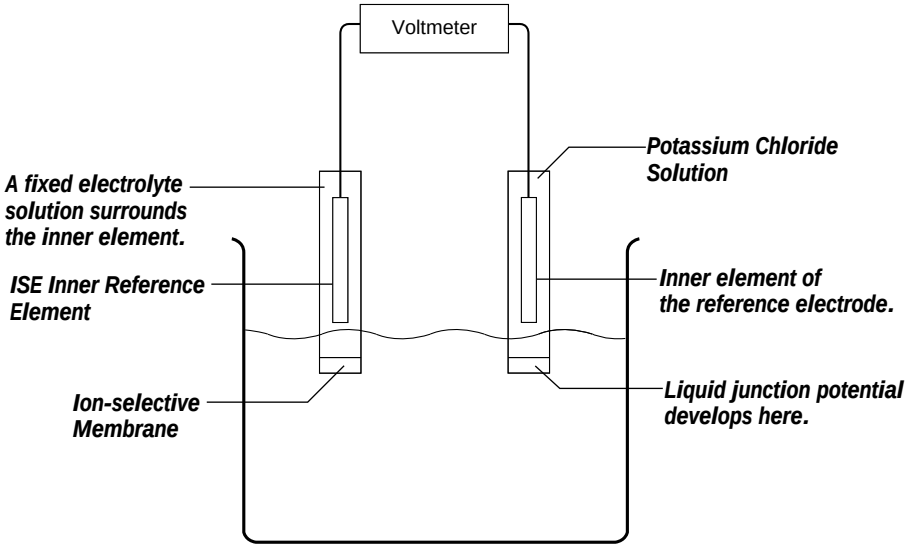
E_{lj} = liquid junction potential

The liquid junction potential (E_{lj}), a small but significant voltage, develops at the liquid junction between the reference electrode, which contains a solution of saturated potassium chloride, and the sample solution. This potential occurs because of the different rates at which chemical species diffuse across the boundary between two liquids. This difference in rates results in a charge separation that gives rise to the liquid junction potential. Although the potential formed is small, it must be considered when measuring cell potential.[9]

System sensors are designed to measure a specific substance in a sample. To better understand the ability of a sensor to measure specific substances, consider ion-selective electrode (ISE) technology. Many of the sensors, like the pH sensor, are designed with this technology. For the purpose of measuring a variety of analytes in solution, sensors must have the ability to measure specific analytes in solution. This ability is known as the recognition mechanism. An ISE contains a specially designed membrane that provides sensor selectivity. Selectivity is the ability of the sensor to interact with a specific ion in solution. The membrane separates an inner, reference element, which is immersed in a fixed electrolyte solution, from the sample.

During analysis, a membrane potential develops as a result of the interaction of the analyte (ion) at the membrane. The membrane potential is related to the amount of substance being measured in the sample. The half-cell potential in the sensor consists of the inner reference element potential plus the membrane potential.

Figure I-2. Ion-Selective Electrode and Reference Electrode



The equation for calculating electrochemical cell potential can be expanded to include the inner reference element and the membrane potential of the ISE.

$$E_{cell} = (E_{ref\ elmt} + E_{memb}) - (E_{ref} + E_{lj})$$

where

E_{cell} = electrochemical cell potential

E_{ref} = reference electrode half-cell potential

$E_{ref\ elmt}$ = potential of the ISE inner reference element

E_{memb} = potential of the ISE membrane

E_{lj} = liquid junction potential

In this equation, the reference electrode potential and the potential of ISE inner reference element are constant; the liquid junction potential can be controlled. Therefore, the potential remaining is the potential generated at the membrane. The membrane potential corresponds to the ion activity and is related directly to the concentration of the ion in solution. The cell potential is expressed quantitatively by the Nernst equation.[9]

$$E_{cell} = K + (2.3\ RT/ZF) \log a_i$$

where

E_{cell} = electrochemical cell potential

K = a constant from various sources such as the liquid junction

R = gas constant

T = absolute temperature

Z = ionic charge

F = Faraday's constant

a_i = activity of the ion in the sample

This equation states that the cell potential is logarithmically related to the activity of the analyte in the sample.

The potential that the sensor actually measures is the activity of the analyte in solution. In clinical chemistry, it is typical that the results be expressed in the concentration of total substance rather that the activity of the substance. For this reason, the measured results must be expressed in units of concentration.

The activity equals the numerical value of the concentration of the ion (mol/L) times the activity coefficient. The activity coefficient is a measure of the degree with which the ion interacts with other ions in solution. The activity coefficient is dimensionless and depends on the ionic strength of the solution.

$$I = 1/2 \sum m * z^2$$

where

I = ionic strength of the solution

z = the charge number of the ions in solution

m = concentration of the ion (mol/L)

The activity coefficient generally decreases with increasing ionic strength.[10]

Using an established convention, the activity of ions that are measured by sensors can be expressed in terms of concentration. This convention contains the assumption that the normal ionic strength of blood plasma water is 160 mmol/kg.[11] Because ionic strength is the primary variable affecting the activity coefficient of ionic species in solution, controlling the ionic strength of calibrating solutions to 160 mmol/kg sets the activity coefficients of ionic species in the calibrating solutions equal to those of blood plasma water at sample ionic strengths close to normal. Both calibrations and the expression of measured quantities may then be made in units of concentration instead of activity.[12]

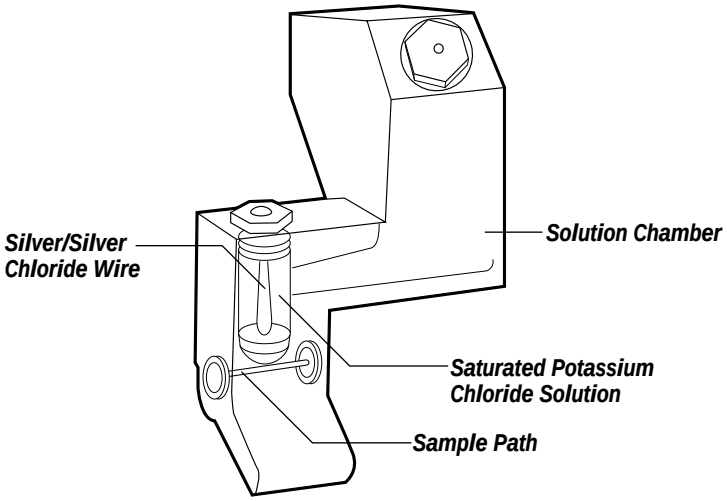
Understanding the Reference Sensor

The reference sensor for the 800 systems works with certain measuring sensors in the measurement module to create an electrochemical cell. It provides a fixed potential, which is independent of analyte activity. The system compares the fixed potential of the reference sensor to the measured potential from the following sensors:

Sensor	System
pH	840, 850, 860
Na^+	850, 860
K^+	850, 860
Cl^-	850, 860
Ca^{++}	850, 860

The reference sensor contains a silver (Ag) wire, coated with a layer of silver chloride (AgCl) and an ion permeable polymer, surrounded by a saturated potassium chloride (KCl) solution. By ensuring that the concentration of Cl^- remains unchanged in the solution, the reference sensor maintains a constant electrical potential. A potassium chloride (KCl) block is in the reference sensor solution chamber to ensure a saturation solution of KCl at 37°C. Refer to Figure I-3.

Figure I-3. Reference Sensor



A permeable cellulose membrane separates the KCl solution from the sample and provides the ionic conduction between the KCl solution and the sample. The membrane completes the conductive path to the sample from the fixed half-cell potential that is required for the measurement.

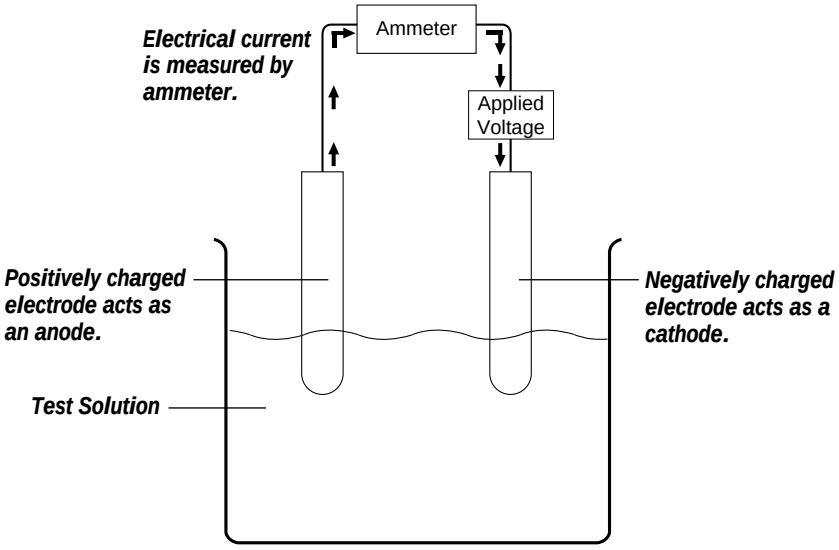
The Ag wire conducts the half-cell potential of the reference sensor to the measurement device where it is compared to the potential of the measuring sensor. The potential difference measured reflects the concentration of analyte in the sample. Although the reference sensor provides a constant potential from sample to sample, the potential difference measured between sensors varies with each sample.

Amperometry

Amperometry is an electrochemical technique used to determine the amount of a specific substance in solution by applying a fixed voltage between two electrodes in an electrochemical cell, and then measuring the current generated as a result of a reaction which produces or consumes electrons (oxidation or reduction, respectively).

The electrochemical cell contains two electrodes: the anode, which is positively charged and the cathode, which is negatively charged. The measuring electrode, which is frequently composed of platinum(Pt) or another noble metal, can be either the anode or the cathode. Each electrode is attached to an external voltage source as shown in Figure I-4.

Figure I-4. Amperometric Cell



As the sample comes in contact with the two electrodes, a known voltage is applied between the anode and the cathode. The analyte to be measured is either an oxidizable or reducible species. If the analyte is an oxidizable species, it will diffuse to the anode where it is oxidized. If the analyte is a reducible species, it will diffuse to the cathode, where it is reduced. In either case, the electrochemical reaction produces a current flow between the anode and cathode that can be measured by a device, such as a milli/micro ammeter. The current measured is directly proportional to the concentration of substance (oxidizable or reducible) present in the sample solution.

pH and Blood Gases

The 800 series systems analyze blood samples for pH, pO_2, and pCO_2.

Hydrogen Ion Activity or pH

The notation of pH expresses the hydrogen ion activity in a solution as the negative logarithm of the hydrogen ion concentration. The hydrogen ion is actually the determinant of the acidity of blood or plasma. Normal cellular metabolism requires an exacting environment where hydrogen ion concentration must be maintained within narrow limits. Hydrogen ion activity reflects the acid-base balance within blood. Acids are substances that donate hydrogen ions; bases are substances that remove hydrogen ions from solution. The lungs, kidneys and blood bases all work to maintain the acid-base status within the strict limits for normal cell functioning.

Expressed in concentration units, hydrogen ion concentrations are very small numbers that are cumbersome to use. (For example the common "neutral" pH of 7.00 is 0.0000001 mol/L.) In 1909 Sorenson[13] converted the numbers mathematically to simplify their use and described the notation pH

$$pH = -\log_{10} cH^+$$

where (H^+) is the molar concentration of hydrogen ions.

Using this formula, a hydrogen ion concentration of 1×10^{-7} mol/L has a pH value of 7. Because pH is the negative logarithm, it's value is inversely proportional to the actual hydrogen ion concentration in a sample. Therefore, as the hydrogen ion concentration decreases, the pH value increases and visa versa.

The normal pH range of human blood is 7.35 – 7.45.

The Henderson-Hasselbalch equation describes how pH expresses the interaction of acid and base in blood.

$$pH = pK + \log \frac{base}{acid}$$

where K is the dissociation constant, which describes the ability to release hydrogen ions.

Since K, and thus pK, is a constant, this equation can be used to demonstrate that pH is proportional to the acid-base concentrations in blood.

$$pH \propto \frac{base}{acid}$$

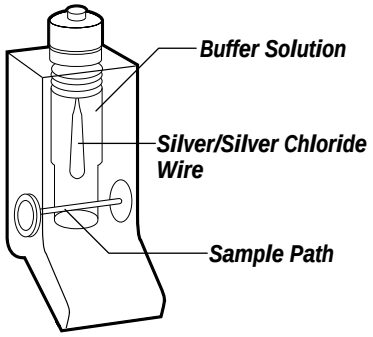
Therefore, if base increases without a corresponding increase in acid, the pH rises, and if acid increases without a corresponding increase in base, the pH decreases.

pH is clinically significant as a means of determining acid-base disturbances. Acid-base disorders can result in several pathologic conditions. An acid-base disorder resulting initially from ventilatory dysfunction is called a primary respiratory acidosis or alkalosis, while a disorder due to renal or gastrointestinal inadequacy is referred to as metabolic acidosis or alkalosis. Using acceptable therapeutic ranges, a pH less than 7.3 indicates acidosis, and a pH greater than 7.5 indicates alkalosis.[14]

pH Sensor

The pH sensor, which is based on ISE technology, is a half-cell that forms a complete electrochemical cell when combined with the external reference sensor. It contains a silver/silver chloride wire surrounded by a buffer solution. A glass membrane that is highly sensitive and specific for hydrogen ions separates the sample from the solution.

Figure I-5. pH Sensor



As the sample comes in contact with the membrane of the pH sensor, a membrane potential develops due to the exchange of hydrogen ions in the membrane. The silver/silver chloride inner conductor transmits the potential to a voltmeter where it is compared to the constant potential of the reference sensor. The final measured potential reflects the hydrogen ion concentration of the sample and is used to report the pH value of the sample.

Carbon Dioxide Tension (pCO_2)

Carbon dioxide (CO_2) is produced during normal cell metabolism and is released into the blood stream where it is transported to the kidneys and lungs for excretion. CO_2 is transported through the blood as bicarbonate (HCO_3^-), dissolved CO_2, and carbonic acid (H_2CO_3). CO_2 exists in a dynamic state in the blood as seen in the following equation:

$$CO_2 + H_2O \leftrightarrows H_2CO_3 \leftrightarrows HCO_3^- + H^+$$

The levels of HCO_3^-, H_2CO_3, and dissolved CO_2 play a major role in maintaining the pH in blood. This relationship is best described through the Henderson-Hasselbalch equation:

$$pH = pK + \log \frac{base}{acid}$$

Substituting HCO_3^- as the base and dissolved CO_2 and H_2CO_3 as the acid, the equation reads as follows:

$$pH \propto \frac{HCO_3^-}{H_2CO_3 + CO_2}$$

Taking the equation further, pH is seen as being proportional to the acid-base relationship:

$$pH \propto \frac{HCO_3^-}{H_2CO_3}$$

Although other acids and bases are present in the blood, the H_2CO_3/HCO_3^- relationship is sensitive and dynamic and typically reflects other acid-base changes.

When the measurement of the partial pressure of carbon dioxide (pCO_2) in the blood is combined with the measured pH, the values can be incorporated into the Henderson-Hasselbalch equation to determine HCO_3^- in addition to the $ctCO_2$. Since the pCO_2 value is proportional to the content of dissolved CO_2/HCO_3^-, the value for pCO_2 can be used along with pH not only to calculate HCO_3^- but also to aid in the differentiation of acid-base abnormalities.

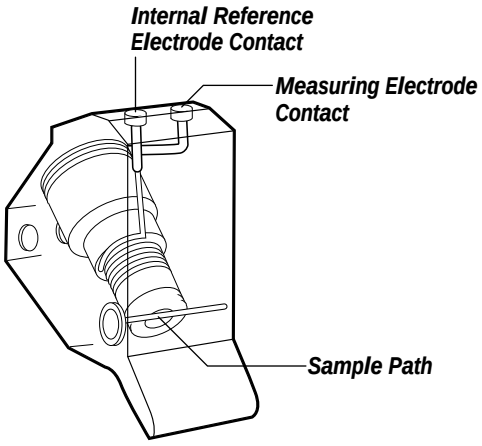
The measurement of pCO_2 is essential in determining ventilatory status. Because the lungs are primarily responsible for controlling pCO_2 levels, changes in pCO_2 reflect respiratory status. For example, an increase in CO_2 indicates decreased ventilation as CO_2 is retained, and a decrease in CO_2 indicates increased ventilation (hyperventilation) as CO_2 is expired from the lungs.

Together, pH and pCO_2 provide a more definitive diagnostic tool in assessing respiratory function. An increase in the pCO_2 value and a decrease in pH indicates respiratory acidosis—a condition in which CO_2 is retained by the lungs. A decrease in the pCO_2 value and an increase in pH indicates respiratory alkalosis—a condition in which the lungs are expiring too much CO_2 relative to the amount produced.

pCO_2 Sensor

The pCO_2 sensor is based upon the electrode described by Severinghaus and Bradley.[15] It is a complete electrochemical cell that consists of a measuring electrode and an internal reference electrode. The measuring electrode, which is a pH electrode, is surrounded by a chloride bicarbonate solution. A membrane permeable to gaseous CO_2 separates this solution from the sample. The internal reference electrode, which contains a silver/silver chloride electrode surrounded by the chloride-bicarbonate solution, provides a fixed potential.

Figure I-6. pCO_2 Sensor



As the sample comes in contact with the membrane, CO_2 diffuses into the chloride-bicarbonate solution, which causes a change in the hydrogen ion activity.

$$CO_2 + H_2O \leftrightarrows HCO_3^- + H^+$$

The internal pH electrode detects the change in hydrogen concentration occurring in the chloride bicarbonate solution and generates a half-cell potential. This potential, when compared to the fixed potential of the reference electrode, results in a measurement that reflects pH change in the chloride bicarbonate solution. The change in pH is related to the log of the partial pressure of CO_2.

Oxygen Tension (pO_2)

Oxygen (O_2) is essential for cell and tissue metabolism in the body. The cardiopulmonary system is responsible for transporting oxygen to the cells. Oxygen transport involves four major steps: convection and diffusion from the air into the pulmonary circulation, combination of O_2 from the lungs with hemoglobin in red blood cells, transportation of the O_2 through the arteries to the cell, and finally the release into the tissues and utilization of O_2 at the cellular level.

Since it is not possible to measure intra-cellular oxygen tension (pO_2), arterial pO_2 has become a standard for clinical evaluation of arterial oxygenation status. Measurement of pO_2(A), which indicates the oxygen tension in arterial blood, reflects the pressure or driving force for moving oxygen from one location to the next due to pressure differential; it is not a measurement of the O_2 content, but it provides a measurement tool to evaluate the pulmonary gas exchange efficiency from an arterial blood sample.

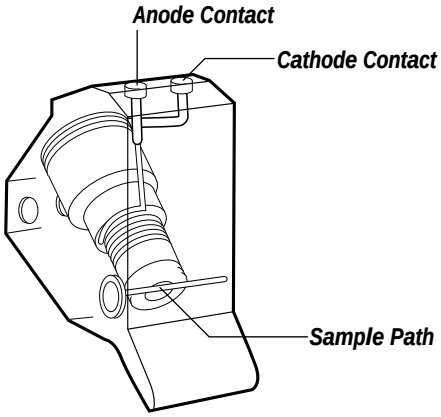
Complete laboratory evaluation of oxygenation often requires much more than simple blood gas measurements. Assessment of ventilatory system and acid-base status is essential to properly interpret clinical significance of arterial oxygenation status. However, many patients can be evaluated and treated successfully using blood gases alone if clinical observations and patient history are taken into account.[16]

The measurement of pO_2 is significant in evaluating the degree of hypoxemia (a deficiency of O_2 in arterial blood) present in a patient. The laboratory reference value for pO_2 is usually 95 mmHg (12.7 kPa) for a healthy young adult living near sea level. However, as with pCO_2 and pH, a wider range of values may occur before any therapeutic action is indicated. Generally a pO_2 of 80 mmHg (10.7 kPa) signals therapeutically significant hypoxemia. Above this value there is very little change in oxygen saturation or oxygen content with changes in oxygen tension, but below it changes in saturation can occur rapidly. Exceptions to this limit are newborns, who have an acceptable range of 40 – 70 mmHg (95.3 – 9.3 kPa) and adults over 50 years old, who have a normal deterioration of lung function that causes a decrease in expected pO_2 values of about 1 mmHg (0.13 kPa) per year.[14]

pO_2 Sensor

The pO_2 sensor is based upon the electrode described by Clark.[17] It is a complete electrochemical cell that incorporates amperometric technology. The sensor consists of a platinum (Pt) cathode, and silver (Ag) anode, an electrolyte solution, and a gas permeable membrane.

Figure I-7. pO_2 Sensor



A constant voltage, called a polarizing voltage, is maintained between the anode and the cathode. As dissolved oxygen from the sample passes through the membrane into the electrolyte solution, it is reduced at the cathode.

$$O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$$

The circuit is completed at the anode, when the Ag is oxidized.

$$4Ag \rightarrow 4Ag^+ + 4e^-$$

The amount of reduced oxygen is directly proportional to the number of electrons gained at the cathode. Therefore, by measuring the change in current (electron flow) between the anode and the cathode, the amount of oxygen in the electrolyte solution is determined.[16]

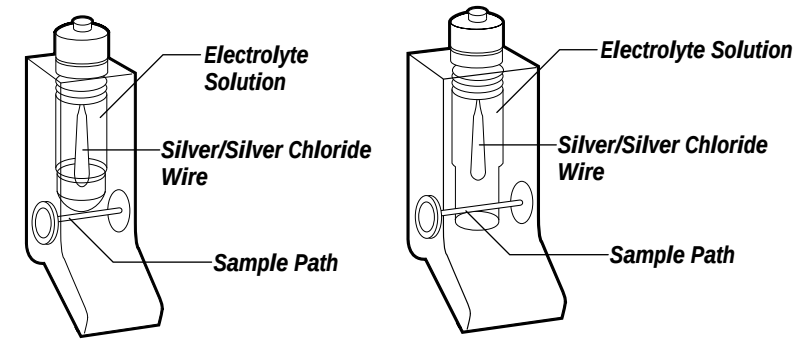
Electrolytes

The 850 and 860 systems analyze blood samples for sodium (Na^+), potassium (K^+), chloride (Cl^-), and calcium (Ca^{++}) in addition to pH and the blood gases. These systems report two additional parameters, the anion gap and a value for calcium adjusted to pH of 7.40. Refer to the section *Other Reported Parameters*, page I-25, for a discussion of these parameters.

The sensors used for electrolytes are based on ion-selective electrode (ISE) technology. Each sensor has a membrane that is highly selective for a specific ion.

Figure I-8 identifies components of the electrolyte sensors. The illustration shows two sensors. One represents the K^+, the Cl^-, and the Ca^{++} sensors, which have similar components. The other represents the Na^+ sensor.

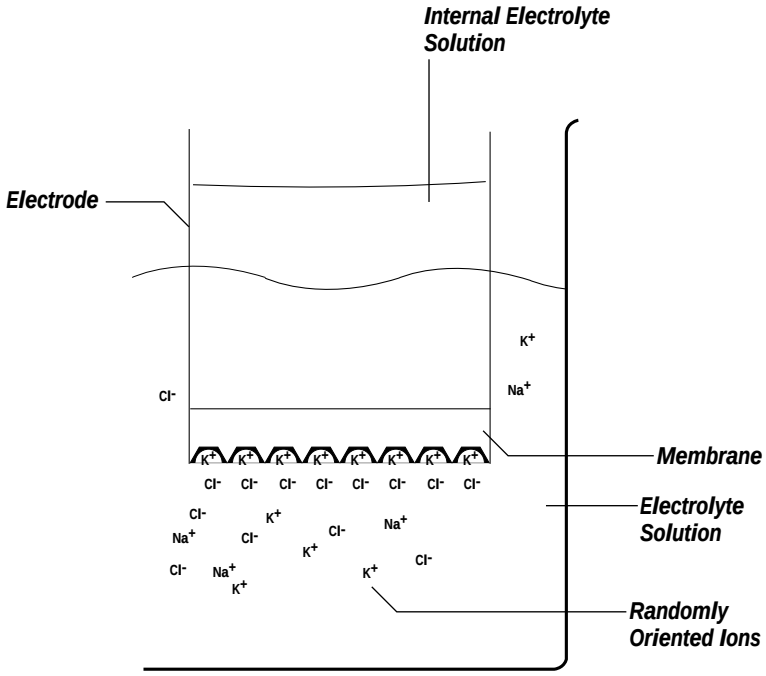
Figure I-8. Electrolyte Sensor Components



Potassium, Chloride, and Calcium Sensor ***Sodium Sensor***

The recognition mechanism in the ISE is the membrane. Each sensor has a membrane selective for the specific substance that it measures. To understand this concept more clearly, take the case of the potassium sensor. The potassium sensor membrane is designed as a charge separator. As shown in Figure I-9, the positively-charged potassium ions selectively interact with the membrane when the sample interfaces with the membrane. The negatively-charged chloride ions do not interact with the membrane. The charge separation causes the membrane potential that is measured by the electrochemical cell.

Figure I-9. Sample Membrane Interface Interaction



Concentration of Sodium

Sodium (Na^+) is the most abundant cation in the extracellular space in the body. It is the major determinant of extracellular osmotic regulation and plays a central role in determining body fluid volume. The kidneys are the primary regulator of sodium and consequently water volume; only minimal amounts of sodium are lost through the skin and other insensible sites. Two regulatory hormones, aldosterone and the antidiuretic hormone (ADH), affect kidney function and hence sodium balance. Aldosterone stimulates the kidneys to reabsorb sodium; ADH stimulates the kidneys to reabsorb water. Maintaining sodium homeostasis is essential in order to regulate body fluids, maintain electrical potential in muscle cells, and control cellular membrane permeability.

Clinically, plasma sodium levels are significant in diagnosing and treating conditions related to sodium imbalance, such as gastroenteritis, vomiting, diarrhea, Addison's disease, and acute renal failure.

Sodium Sensor

The sodium sensor is a half-cell that combines with the external reference sensor to form a complete electrochemical cell. The sensor contains a silver/silver chloride wire surrounded by an electrolyte solution that has a fixed concentration of sodium and chloride ions. The membrane, a specially formulated glass capillary that is highly selective for sodium ions over other clinically encountered cations, separates the electrolyte solution from the sample.

As the sample comes in contact with the membrane of the sensor, a potential develops due to the exchange of sodium ions in the membrane. The potential developing across the membrane is compared to the constant potential of the external reference sensor. The final measured potential is proportional to the sodium ion concentration in the sample. The potential developed by the electrochemical cell varies with the ion activity in each sample.

Concentration of Potassium

Potassium (K^+) is the major intracellular cation. It plays an important role in maintaining cell membrane potential in neuromuscular tissue. The normal level within cells is 150 mmol/L, while the normal extracellular potassium level is only 4 mmol/L. A depletion of extracellular potassium causes an increase in the transmembrane electrical potential gradient, which impedes the impulse formation and propagation involved in muscle contraction.

Most potassium is excreted by the kidney, which is the major regulator of potassium output in the body. Actually, the kidney is better at conserving sodium and excreting potassium so in cases where potassium intake stops, the kidney requires time to adjust and stop excreting potassium. Two hormones, insulin and aldosterone can affect the extracellular level of potassium. Both insulin and aldosterone influence intercellular uptake of potassium, while aldosterone causes increased potassium excretion through the kidney.

Because the serum level of potassium is so small, minor changes can have significant consequences. Therefore, monitoring potassium levels is important especially in patients who are undergoing surgery, or who are experiencing cardiac arrhythmias or acute renal failure, and who are being treated with diuretics. Additionally, regulating serum potassium is significant in cardiac patients who are receiving digitalis therapy since hypokalemia can increase cardiac sensitivity to digoxin.[18]

Potassium Sensor

The potassium sensor is a half-cell that combines with the external reference sensor to form a complete electrochemical cell. The sensor contains a silver/silver chloride wire surrounded by an electrolyte solution that has a fixed concentration of potassium ions. The membrane, which consists of the ionophore valinomycin immobilized in a plasticized PVC (polyvinyl chloride) matrix, separates the electrolyte solution from the sample. Valinomycin is a neutral ion carrier that is highly selective for potassium ions over other clinically encountered cations.

As the sample comes in contact with the membrane of the potassium sensor, a membrane potential is created by the interaction of potassium ions with the membrane. The potential developing in the potassium sensor is compared to the constant potential of the external reference sensor. The final measured potential is directly proportional to the potassium ion concentration in the sample. The potential developed by the electrochemical cell varies with the ion activity in each sample.

Concentration of Chloride

Chloride (Cl^-) is the major extracellular anion in the body. It plays a large role in maintaining electrical neutrality and normal osmolality, and it participates in the regulation of acid-base balance. The kidneys are the main regulator of chloride in the body. Serum levels of chloride usually correspond to increases and decreases of sodium. Clinically, the serum chloride level alone is rather meaningless. A change in chloride level does not reveal much about a patient's condition; it must be viewed as part of the overall fluid and electrolyte status.

Hypochloremia is usually seen in states of hyponatremia. However in pyloric stenosis, chloride levels are usually proportionally lower than sodium levels. Hyperchloremia is seen in cases of excessive administration of chloride and in renal failure. Additionally, because the chloride level remains fairly constant, it is valuable in the calculation of the anion gap.

Chloride Sensor

The chloride sensor is a half-cell that combines with the external reference sensor to form a complete electrochemical cell capable of measuring chloride concentration in a sample. The sensor contains a silver/silver chloride wire surrounded by an electrolyte solution that has a fixed concentration of chloride ions. The membrane is a derivitized quaternary ammonium compound that is immobilized in a polymer matrix. It acts as an ion exchanger with a high selectivity for chloride ions over other ions present in the sample, and separates the electrolyte solution from the sample.

As the sample comes in contact with the membrane of the chloride sensor, chloride ion exchange occurring at the membrane, creates a membrane potential. The potential that develops in the chloride sensor is compared to the constant potential of the external reference sensor. The final measured potential is directly proportional to the chloride ion concentration in the sample. The potential developed by the electrochemical cell varies with the ion activity in the sample.

Concentration of Ionized Calcium

Ionized calcium (Ca^{++}) is the physiologically active form of calcium, which comprises approximately 45% of the total calcium in plasma. It is essential for the contractility of smooth vascular muscle, and, it plays a vital part in cardiovascular function. It is also important in muscle function, nerve function, and bone formation, and it is a cofactor in many cellular hormone and enzyme reactions.

The action of the parathyroid hormone (PTH)—1,25 dihydroxyvitamin D (1,25D)—and calcitonin closely controls the concentration of calcium in extracellular fluid, and regulates the transport of calcium across the gastrointestinal tract, kidney, and bone. Calcium is one of the most tightly controlled analytes in the body with fluctuations of less than 5% occurring about the mean during a 24-hour period.[19]

Clinically, hypocalcemia can result from a deficiency of PTH or 1,25 D, which can be caused by malabsorption of vitamin D, hypoparathyroidism, or chronic renal failure. Hypercalcemia, which occurs more frequently than hypocalcemia, is commonly caused by primary hyperparathyroidism and malignant disease. The elevated calcium resulting from both of these conditions can produce abnormal cardiovascular rhythms.

In critical care situations, especially where large amounts of blood are being transferred, ionized calcium levels should be monitored closely. Transfused blood typically contains citrate as an anticoagulant that can bind ionized calcium and affect its level in the blood. Although total calcium levels may increase, ionized calcium may decrease and lead to cardiac and neuromuscular malfunction.

When measuring ionized calcium, pH should also be measured. Because hydrogen ions compete with calcium for calcium binding sites, a change in sample pH can have a direct effect on calcium levels. For example, a change in pH of 0.1 can cause a change in calcium of 0.2 mg/dL, which exceeds the span of the normal range. Its effects, if not taken into account, are clearly significant.[20]

Calcium Sensor

The calcium sensor is a half-cell that combines with the external reference sensor to form a complete electrochemical cell capable of measuring calcium levels in a blood sample. The sensor contains a silver and silver chloride wire surrounded by an electrolyte solution that has a fixed concentration of calcium ions. A membrane, consisting of an ionophore imbedded in a polyvinyl chloride membrane, separates the electrolyte solution from the sample. The ionophore is a compound that is highly selective for calcium ions over other ions.

When the sample comes in contact with the membrane of the measuring sensor, a membrane potential develops as calcium ions interact with the membrane. This membrane potential is compared to the constant potential of the external reference sensor. The final measured potential is proportional to the calcium ion concentration in the sample. The potential developed by the electrochemical cell varies with the ion activity in each sample.

Metabolites

The 860 system analyzes blood samples for glucose and lactate in addition to pH, blood gases, and electrolytes.

Concentration of Glucose

Glucose is the fundamental molecule in carbohydrate metabolism. Carbohydrates, which provide a major food supply and energy source for the body, are broken down into simple sugars such as glucose. Glucose is then absorbed through the intestine, passes through the liver, and eventually enters the vascular system where it reaches the cell level to be used as fuel.

A number of factors influence the level of blood glucose. Dietary intake has a direct effect of glucose concentration. Blood levels of glucose will fluctuate depending on nutritional condition and the time of day when a sample is taken. Insulin, a hormone produced by specialized cells in the pancreas, plays an important role in regulating the blood level of glucose. By promoting glycogenesis (conversion of glucose to glycogen) and by increasing the permeability of cells to glucose, insulin can decrease blood glucose levels.

Determining the blood glucose level is helpful in diagnosing many metabolic diseases. Hyperglycemia is usually equated with diabetes mellitus where the pancreas fails to supply sufficient insulin to control glucose levels. However, other conditions such as Cushing's disease, hyperthyroidism, pancreatitis, and diuretic therapy can also cause an increase in glucose levels. Hypoglycemia is most frequently caused by over administration of insulin. Other causes of low blood glucose levels include Addison's disease, hypopituitarism, and severe liver disease.

Concentration of Lactate

Lactate acid is an intermediary product of the anaerobic metabolism of glucose. Glycolysis is the term commonly used to describe the conversion of glucose to lactic acid. Under normal circumstances, glycolysis occurs during muscle contraction where the rate of metabolism outpaces the oxygen supply in the cells. During strenuous exercise, the level of lactic acid increases significantly and passes to the blood where it is transported to and metabolized by the liver. In normal aerobic conditions the lactic acid is readily oxidized in the cell to pyruvic acid, which is eventually degraded to CO_2 and H_2O.

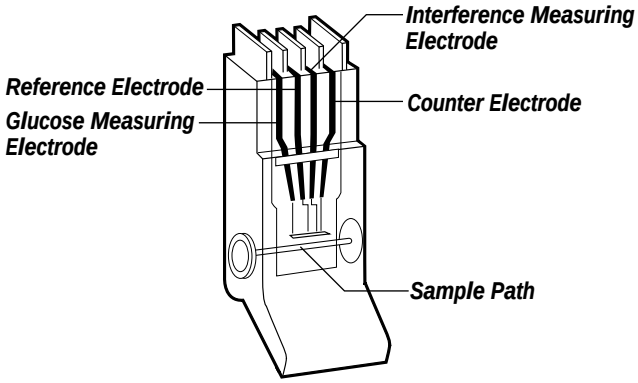
The concentration of lactate in the blood is affected by the rate of production, the rate of metabolism, and the availability of oxygen at the cell level.

Determining the blood lactate level is helpful in assessing the supply of oxygen at the tissue level. Increased oxygen deprivation causes the normal oxidation of pyruvic acid to lactate and can cause severe acidosis called lactic acidosis. This condition is characterized by increased lactate levels and increased lactate:pyruvic ratio in the blood due to the lack of cellular oxidative process. Additionally, increased lactate levels are seen in hypoxia with hypoxemia as seen in shock, cardiac decompensation, and pulmonary insufficiency. Finally, because the liver plays a significant role in lactate metabolism, decreased liver perfusion will result in increased lactate levels.

Glucose and Lactate Biosensors

The glucose and lactate biosensors are complete electrochemical cells that incorporate amperometric technology to measure glucose or lactate concentration in samples. The biosensors consist of four electrodes.* The measuring electrode contains platinum and glucose oxidase or lactate oxidase in a binder, while the reference electrode is composed of Ag/AgCl. Two other electrodes are also present. The counter electrode is a Pt (platinum) conductor that ensures a constant applied potential. Another measuring electrode, without the enzyme, determines interfering substances in the sample. The potential from interfering substances is removed from the total differential measurement. A microporous cover membrane separates the electrodes from the sample.

Figure I-10. Biosensor



A constant voltage, called a polarizing voltage, is maintained during analysis. In the glucose sensor, glucose from the sample interacts with the glucose oxidase on the surface of the measuring electrode to form hydrogen peroxide and gluconic acid

$$\underset{\text{(glucose)}}{C_6H_{12}O_6} + H_2O + O_2 \xrightarrow{\text{GOX}} \underset{\text{(gluconic acid)}}{C_6H_{12}O_7} + H_2O_2$$

where GOX is the glucose oxidase.

The polarizing voltage is sufficient to cause oxidation of the hydrogen peroxide to oxygen.

$$H_2O_2 \rightarrow 2H^+ + O_2 + 2e^-$$

---

* Platinized activated carbon electrode technology license from Cambridge Life Sciences plc. under U.S. Patent Nos. 4,970,145 and 5,160,418 and foreign counterparts.

The loss of electrons in the oxidation of H_2O_2 creates a current flow that is directly proportional to the lactate concentration in the sample.

In the lactate sensor, lactic acid from the sample interacts with the lactate oxidase on the surface of the measuring electrode to form pyruvic acid and hydrogen peroxide

$$\underset{\text{(lactic acid)}}{C_3H_6O_3} + H_2O + O_2 \xrightarrow{\text{LOD}} \underset{\text{(pyruvic acid)}}{C_3H_4O_3} + H_2O_2$$

where LOD is the lactate oxidase.

The polarizing voltage is sufficient to cause oxidation of the hydrogen peroxide to oxygen.

$$H_2O_2 \rightarrow 2H^+ + O_2 + 2e^-$$

The loss of electrons in the oxidation of H_2O_2 creates a current flow that is directly proportional to the lactate concentration in the sample.

Hemoglobin and its Derivatives

Hemoglobin analysis yields important information necessary to assess the function of the oxygen transport system. The need for hemoglobin determinations has led to the development of a number of methods to determine the concentration of total hemoglobin, hemoglobin derivatives, and dyshemoglobins in whole blood. The presence of dyshemoglobins and toxins changes the oxygen binding capacity of hemoglobin and therefore its ability to transport oxygen.[33]

Hemoglobin is a tetrameric protein consisting of two pairs of polypeptide chains, each chain having a heme group containing one atom of iron. Each molecule of hemoglobin can bind up to four molecules of oxygen, one at each heme group. Hemoglobin has a key role in the transport of oxygen from the lungs to the tissues and the transport of carbon dioxide from the tissues to the lungs.

Hemoglobin's ability to bind and release oxygen depends on several factors:[37] pH, pCO_2, pO_2, 2, 3–diphosphoglycerate concentration, temperature.

The presence of dyshemoglobins (that is, hemoglobins not available for reversible binding with oxygen), such as carboxyhemoglobin, methemoglobin, and sulfhemoglobin, as well as abnormal concentrations of hemoglobin variants, such as fetal hemoglobin, may also affect the normal oxygen transport mechanism.[38]

Hyperlipemia can result in artificially increased methemoglobin values.[42, 43] High bilirubin concentrations can falsely increase oxyhemoglobin values. Hyperlipemia and administration of fat emulsions can increase total hemoglobin values. Samples frozen with liquid nitrogen can have decreased total hemoglobin levels.[43] Samples from patients receiving blood substitutes yield unreliable results for oxygen content blood due to the different oxygen solubility of the blood substitutes.

Total Hemoglobin

Total hemoglobin (tHb) is the total of all measured hemoglobin fractions.[38] Total hemoglobin determination is important in the assessment of oxygen transport and in the evaluation of anemia. The total hemoglobin reference range for a normal adult population is 12.0 to 18.0 g/dL.

Total hemoglobin in the CO-ox module is determined using the following equation:

$$\text{tHb} = F\text{O}_2\text{Hb} + F\text{HHb} + F\text{MetHb} + F\text{COHb}$$

Oxyhemoglobin

Oxyhemoglobin (O_2Hb) is the fraction of hemoglobin that is reversibly bound to oxygen.[38] The oxyhemoglobin reference range for arterial blood for a normal population is 94.0 to 97.0%.

The percent of oxyhemoglobin is determined using the following equation:

$$F\text{O}_2\text{Hb} = \frac{c\text{O}_2\text{Hb}}{\text{ctHb}} \times 100$$

Deoxyhemoglobin

Deoxyhemoglobin (HHb) refers to the hemoglobin capable of binding oxygen. Deoxyhemoglobin is sometimes referred to as reduced hemoglobin.[38] The deoxyhemoglobin reference range for arterial blood for a normal population is 0.0 to 5.0%.

The percent of deoxyhemoglobin is determined using the following equation:

$$F\text{HHb} = \frac{c\text{HHb}}{\text{ctHb}} \times 100$$

Methemoglobin

Methemoglobin (MetHb), which is sometimes known as hemoglobin Hi, is hemoglobin whose iron is oxidized to its ferric state (FE(111) and is unable to bind oxygen. High methemoglobin concentrations, a condition called methemoglobinemia, can produce hypoxia and cyanosis. Methemoglobinemia can be the result of hereditary conditions or of exposure to toxic substances such as nitrates, nitrites, aniline dyes and their derivatives and topical anesthetics such as benzocaine.[39,41] Infants and other individuals with significant fetal hemoglobin concentrations show increased susceptibility to methemoglobinemia because fetal hemoglobin converts to methemoglobin more readily than adult hemoglobin.[27,40] The methemoglobin reference range for arterial or venous blood for a normal population is 0.0 to 1.5%.

The percent of methemoglobin is determined using the following equation:

$$F\text{MetHb} = \frac{\text{cMetHb}}{\text{ctHb}} \times 100$$

Carboxyhemoglobin

Carboxyhemoglobin (COHb) is hemoglobin covalently bound to carbon monoxide. Hemoglobin has over 200 times greater affinity for carbon monoxide than for oxygen. Hemoglobin bound to carbon monoxide is unavailable for oxygen transport, and high levels of carboxyhemoglobin result in hypoxia and cyanosis, which can be fatal.

The carboxyhemoglobin reference range for a normal population is 0.0 to 1.5%. While the amount of carboxyhemoglobin in the blood of healthy nonsmokers is very small (between 0.1% and 0.4%), smoking, air pollution, and occupational exposure to carbon monoxide affect COHb levels.[39]

The percent of carboxyhemoglobin is determined using the following equation:

$$F\text{COHb} = \frac{\text{cOHb}}{\text{ctHb}} \times 100$$

Sulfhemoglobin

Sulfhemoglobin (SulfHb) is a stable compound of hemoglobin and sulfur. Sulfhemoglobin has an extremely low affinity for oxygen and may often be accompanied by methemoglobinemia. The presence of sulfhemoglobin affects oxyhemoglobin values and other quantities if its absorbance spectrum is not accounted for.[39] The sulfhemoglobin reference range for a normal population is 0.0 to 2.2%.

The CO-oximeter (CO-ox) module detects and indicates concentrations of sulfhemoglobin greater than 1.5%.

Determination of Hemoglobin Derivatives

Hemoglobin derivatives have characteristic absorbance spectra; that is, each derivative absorbs light differently at different wavelengths. Similarly, interfering substances also absorb light at known wavelengths.

The spectral absorption method determines concentration using matrix equations. For each substance or fraction, the absorbance at a specific wavelength is equal to the product of the path length, concentration of the fraction or substance, and the molar absorptivity or the extinction coefficient for that substance, as shown in the following equation:

$$A_x = \varepsilon_1 C_1 + {}_2C_2 + \ldots {}_nC_n$$

where A_x is the absorbance at a specific wavelength, ε is the major extinction coefficient for that fraction or substance at a specific wavelength, and C is the concentration of the substance.

These equations are based on the work of VanAssendelft[33,34] and Benesch, Benesch, and Yung.[35]

800 Series CO-oximeter Module

The 800 systems CO-oximeter (CO-ox) module measures the light of whole blood at several wavelengths. Based on this, the CO-ox module measures and reports total hemoglobin and other related quantities. The CO-ox module also detects the presence of interfering substances such as bilirubin, cyanmethemoglobin, turbidity, and dyes.

The CO-ox module is connected to the base model, which supplies power to the module. The CO-ox module contains measuring, fluidic, and electronic components. It uses the sample entry port, reagents, and waste components of the base model.

The measurement system for the CO-ox module detects and quantitates the analytes present in the sample. The measurement system has the following components:

- the lamp
- the illumination optics (lenses and filters)
- the fiber optic coupler
- the sample chamber

- the polychromator—which consists of coupling lenses, entrance slot, collimating mirror, grating camera mirror, and the diode array

Light from the lamp passes through the lenses, a series of filters, and the fiber optic coupler to the sample chamber. The light is coupled from the sample chamber, by a second pair of lenses, to the polychromator. In the polychromator, light is collimated by the first mirror and is diverted to the grating which separates the light into a continuous spectrum of wavelengths. The spectrum of light is focused by the second mirror to the diode array where the intensities at several wavelengths are measured.

The sample chamber is located between the fiber optics and the polychromator. After passing through the hemolyzer, the sample flows through tubing into the sample chamber, where the sample is warmed to 37°C and then measured. The sample chamber also acts a fluid detector, sensing when sufficient sample reaches the chamber for measurement.

Other Reported Parameters

This section describes the specific reported parameters generated by the 800 system. The parameters are all based on NCCLS/IFCC recommendations unless otherwise noted.

Bicarbonate Ion (HCO_3^-)

The bicarbonate ion (HCO_3^-) is the major buffer substance present in the body, and plays a major role in maintaining the pH level in blood. It is present in large amounts in the blood as a result of the dynamic state of CO_2 in the blood. CO_2 is transported through the blood as bicarbonate (HCO_3^-), dissolved CO_2, and carbonic acid (H_2CO_3). The following equation describes the dynamic state of CO_2 in blood:

$$CO_2 + H_2O \leftrightarrows H_2CO_3 \leftrightarrows HCO_3^- + H^+$$

The majority of CO_2 is transported as HCO_3^-. Its role as a base is seen through the Henderson-Hasselbalch equation:

$$pH = pK + \log \frac{base}{acid}$$

Substituting HCO_3^- as the base and dissolved CO_2 and H_2CO_3 (which equals $0.0307\ pCO_2$) as the acid, the equation reads as follows:

$$pH = pK + \log \frac{[HCO_3^-]}{0.0307\ pCO_2}$$

where pK, which is the dissociation constant describing the ability to release hydrogen ions, equals 6.105 for normal plasma, and 0.0307 is a combination of CO_2 solubility in plasma and a factor for converting mmHg to mmol/L.

The equation can be further developed to show pH as proportional to the acid-base relationship:

$$pH \propto \frac{HCO_3^-}{H_2CO_3}$$

The equation clearly demonstrates the HCO_3^-, pH relationship. As HCO_3^- increases the pH increases, and as HCO_3^- decreases the pH decreases.[21]

The kidneys are the major controller of the bicarbonate ion. Bicarbonate levels are clinically significant in helping to determine the non-respiratory, renal (metabolic) component in acid-base disorders.

Changes in HCO_3^- levels along with pH values can help determine whether acidosis and alkalosis disorders are metabolic in origin. In metabolic acidosis, HCO_3^- levels decrease causing an increase in H^+ which leads to a decrease in pH. Conversely, in metabolic alkalosis, HCO_3^- levels increase, causing a decrease in H^+, which leads to an increase in pH.

There are two versions of bicarbonate, the actual value and the standard value. The 800 system lets you select the bicarbonate equations to apply to patient results. You can select the equation for actual bicarbonate, standard bicarbonate, or both.

Actual Bicarbonate (HCO_3^-act)

Solving the Henderson-Hasselbalch equation for bicarbonate ion concentration results in the following equation, which is based on the National Committee for Clinical Laboratory Standards (NCCLS) recommendations,[32] for actual bicarbonate:

$$\log cHCO_3^- = pH + \log (pCO_2 \times 0.0307) - 6.105$$

Standard Bicarbonate (HCO_3^-std)

The equation described by VanSlyke and Cullin[23] is used for calculating standard bicarbonate:

$$[HCO_3^-] = 24.5 + 0.9A + (A - 2.9)^2 (2.65 + 0.31ctHb)/1000$$

where

$$A = BE(B) - 0.2\ [ctHb]\ [100 - O_2SAT]/100$$

The *c*tHb value can be entered during sample analysis or it can be a value defined in setup.

Base Excess

Base excess is an empirical expression that approximates the amount of acid or base required to titrate one liter of blood back to a normal pH of 7.40. The base excess in blood with a pH of 7.40, a pCO_2 of 40 mmHg (5.33 kPa), a total hemoglobin of 15.0g/dL and a temperature of 37.0°C is zero. Base excess is useful in the management of patients with acid-base disorders as it permits the estimation of the number of equivalents of sodium bicarbonate or ammonium chloride required to correct the patient's pH to normal.

There are two versions of base excess, the base excess of extracellular fluid [BE(ecf)] and the base excess of blood [BE(B)]. In the setup options, you can select the version you want to use for displayed results, and you can select one or both for printing on all patient reports.

The calculations for both versions of base excess are derived from the following relationships, which are based on the NCCLS recommendations.[22]

Base Excess of Extracellular Fluid [BE(ecf)]

The base excess of extracellular fluid, formerly known as *in vivo* base excess, reflects only the nonrespiratory component of pH disturbances.

$$BE(ecf) = cHCO_3^- - 24.8 + 16.2\ (pH - 7.40)$$

Base Excess of Blood [BE(B)]

The base excess of blood, formerly known as *in vitro* base excess, is calculated from the following equation.

$$BE(B) = (1 - 0.014 \times ctHb)\ [(cHCO_3^- - 24.8) + (1.43 \times ctHb + 7.7)(pH - 7.40)]$$

The *c*tHb value can be entered during sample analysis or can be a value defined in setup.

Oxygen Saturation (Estimated)

Oxygen saturation is a ratio, expressed as a percentage of the volume of oxygen carried to the maximum volume that can be carried by the hemoglobin. Knowledge of oxygen saturation, when combined with knowledge of oxygen content, is useful for evaluating the amount of oxygen actually available for the tissues and can be used to determine the effectiveness of oxygen therapy.

Oxygen saturation can be directly measured or it can be estimated using the relationship described by Kelman[24] and Thomas[25]:

$$O_2SAT = \frac{N^4 - 15N^3 + 2045N^2 + 2000N}{N^4 - 15N^3 + 2400N^2 - 31{,}100N + (2.4 \times 10^6)} \times 100$$

where $N = pO_2 \times 10^{[0.48(pH-7.4) - 0.0013\ BE(B)]}$ and BE(B) is calculated assuming 100% oxygen saturation.

Since oxygen saturation also depends upon the level of carbon monoxide and 2,3 diphosphoglycerate (2,3 DPG) in the blood, the calculated value for oxygen saturation may not be equal to the measured value in patients with abnormal levels of 2,3 DPG or carbon monoxide. The equation does not account for these variations, therefore, the oxygen saturation that is reported should only be used as an estimate of the actual oxygen saturation.

NOTE: Clinically significant errors can result from incorporation of an estimated value for oxygen saturation in further calculations, such as oxygen content and shunt fraction (Q_{sp}/Q_t), or by assuming that the value obtained is equivalent to fractional oxyhemoglobin.[26]

Hemoglobin Oxygen Saturation

Hemoglobin oxygen saturation (sO_2) is a ratio of the amount of hemoglobin bound to oxygen to the total amount of hemoglobin able to bind oxygen.[38] Hemoglobin oxygen saturation, with oxygen content and oxygen capacity, is a useful parameter for determining the amount of oxygen in the blood that is actually available to the tissues and for determining the effectiveness of oxygen therapy. The hemoglobin oxygen saturation reference range for arterial blood for a normal population is 92.0 to 98.5%.

Hemoglobin oxygen saturation, expressed as a percent, is determined using the following equation:

$$sO_2 = \frac{O_2Hb}{O_2Hb + HHb} \times 100$$

Oxygen Content (Estimated)

Oxygen content is the concentration of the total oxygen carried by the blood, including oxygen bound to hemoglobin as well as oxygen dissolved in plasma and in the fluid within red cells.

Clinically, dissolved oxygen is unimportant for most situations. However, at very low levels of hemoglobin or in patients receiving hyperbaric oxygen therapy, dissolved oxygen may be a very significant contributor to oxygen content and thus to oxygen transport.

Oxygen content is determined, using NCCLS recommendations,[26] from the following relationship:

$$ctO_2 = FO_2Hb \times 1.xx \times ctHb + 0.00314 \times pO_2$$

where *c*tHb is expressed in g/dL.

If FO_2Hb is unavailable, oxygen content is derived from estimated oxygen saturation (O_2SAT) according to the following equation:

$$O_2CT = O_2SAT \times 1.39 \times ctHb + .00314 \times pO_2$$

If *c*tHb is not measured or entered,O_2CT is not displayed or printed.

NOTE: Clinically significant errors can result from incorporation of an estimated value for oxygen saturation in further calculations, such as oxygen content and shunt fraction (Q_{sp}/Q_t), or by assuming that the value obtained (O_2SAT) is equivalent to fractional oxyhemoglobin.[26]

Oxygen Content of Hemoglobin

The oxygen content of hemoglobin, $ctO_2(Hb)$, is the volume of oxygen actually bound to hemoglobin.[38] The oxygen content of hemoglobin, with hemoglobin oxygen saturation and oxygen capacity, is a useful parameter for determining the amount of oxygen in the blood that is actually available to the tissues and for determining the effectiveness of oxygen therapy. The oxygen content reference range for arterial blood for a normal population is 15.0 to 23.0 mL/dL.

The oxygen content of hemoglobin for a sample analyzed only for CO-ox parameters on an 800 system is determined using the following equation:

$$ctO_2\,(Hb) = 1.xx \times FO_2Hb \times ctHb$$

where 1.xx represents the oxygen binding factor of hemoglobin and is a value in the range of 1.30 to 1.40 as specified in the CO-ox module setup.

The oxygen content of a sample analyzed for blood gas and CO-ox parameters on an 800 system is determined using the following equation:

$$ctO_2\,(B) = 1.xx \times FO_2Hb \times ctHb + 0.00314 \times pO_2$$

where the additional equation component represents the dissolved oxygen (0.00314 is the solubility coefficient).

Oxygen Capacity of Hemoglobin

The oxygen capacity of hemoglobin (BO_2 or O_2CAP) is the maximum amount of oxygen that the hemoglobin in a given quantity of blood can carry. This value represents the potential of hemoglobin to bind to oxygen and includes all the oxygen that can be bound to the available hemoglobin.[38] The oxygen capacity of hemoglobin, with hemoglobin oxygen saturation and oxygen content, is a useful parameter for determining the amount of oxygen in the blood that is actually available to the tissues and for determining the effectiveness of oxygen therapy. The oxygen capacity reference range for arterial blood for a normal population is 17.6 to 23.6 mL/dL.

The oxygen capacity of hemoglobin is determined using the following equation:

$$O_2CAP = 1.xx \frac{FO_2Hb + FHHb}{100} \times ctHb$$

where 1.xx represents the oxygen binding factor of hemoglobin and is a value in the range of 1.30 to 1.40 specified in the CO-ox module setup

p50

Half saturation of hemoglobin by oxygen ($p50$) indicates the partial pressure of oxygen when oxygen has saturated 50% of the available hemoglobin. The $p50$ value indicates the position of the oxygen-hemoglobin dissociation curve.[27] Unless a CO-oximeter is connected to the 800 system, $p50$ is an entered value only.

- low $p50$ shifts the curve to the left and indicates increased oxygen-hemoglobin affinity
- high $p50$ shifts the curve to the right and indicates decreased oxygen-hemoglobin affinity

The $p50$ value is useful in indicating the presence of abnormal hemoglobin that affects the oxygen transport mechanism, and as an indirect measure of the 2,3 DPG concentration. It can also indicate changes in pH, pCO_2, and temperature.[26,27]

The $p50$ value is reported for sO_2 values between 20% and 90% and is determined using the following equation:

$$p50 = 26.6\,(pO_2 \times 10^{-0.48(7.4-pH+0.0013BEvt)})/pO_2S$$

where pO_2 = measured pO_2 corrected to 37°C and pH 7.4, and pO_2S = pO_2 corresponding to measured sO_2 calculated as follows:[31]

$$sO_2 = \sum_{i=0}^{i=7} K_{i+1}\,[(pO_2S - 27.5)/(pO_2S + 27.5)]^i$$

$K_1 = 51.87074$
$K_2 = 129.8325$
$K_3 = 6.82836$
$K_4 = -223.7881$
$K_5 = -27.953$
$K_6 = 258.5009$
$K_7 = 21.84175$
$K_8 = -119.2322$

Total Carbon Dioxide ($ctCO_2$)

Total carbon dioxide ($ctCO_2$), in combination with pH and pCO_2, is useful in distinguishing between metabolic and respiratory acid-base disorders.

Carbon dioxide exists in several forms in blood plasma, but only two forms, dissolved CO_2 and HCO_3^-, are quantitatively significant. Based on NCCLS recommendations,[22] the following equation is used:

$$ctCO_2 = cHCO_{3-} + (0.0307 \times pCO_2)$$

Hematocrit

Hematocrit (Hct) is the ratio of the volume of packed red blood cells to the volume of whole blood.[53] Hematocrit, with other parameters such as total hemoglobin, is useful in the evaluation of anemia. The hematocrit reference range for a normal population is 35.0 to 53.0 g/dL.

The estimated hematocrit value is determined using the following equation:

$$Hct = ctHb \times 2.941$$

where 2.941 is a factor calculated by dividing 100 g/dL by a normal MCHC (mean corpuscular hemoglobin concentration) of 34%.

Estimated hematocrits should not be used as the sole consideration in the diagnosis of hematological disorders.

Patient Temperature Correction

All measurements and calculations are based upon a standard temperature of 37.0°C. During sample analysis, you can enter the actual patient temperature value, which enables the system to provide temperature corrected results. The following equations, based on NCCLS recommendations,[22] are used:

$$\text{pH correction} = \Delta\,\text{pH}/\Delta\text{T} = -0.0147 + 0.0065\,(7.4 - \text{pH})$$

$$p\text{CO}_2\ \text{correction} = \frac{\Delta \log p\text{CO}_2}{\Delta\,\text{T}} = 0.019$$

$$p\text{O}_2\ \text{correction} = \frac{\Delta \log p\text{O}_2}{\Delta\,\text{T}} = \frac{5.49 \times 10^{-11} \times p\text{O}_2^{3.88} + 0.071}{9.72 \times 10^{-9} \times p\text{O}_2^{3.88} + 2.30}$$

Gas Exchange Indices

Gas exchange indices are a quick way to estimate the relationship between pulmonary dysfunction and the hypoxia, and to quantitatively determine the degree of pulmonary shunting. The primary benefit of using gas exchange indices, is that they are easy to derive at the bedside. However, they do not have a high level of correlation with the actual measurement of arterial and mixed venous blood and should be used with discretion. A more reliable method is the Q_s/Q_t shunt fraction, which is based on measurements of $p\text{O}_2$ and oxygen content.

The gas exchange indices are provided with the 800 system for convenience. Final judgment of their use is in the hands of the physician.

All gas exchange indices require an arterial sample and use measured values at patient temperature.

Alveolar Oxygen Tension

Alveolar oxygen tension, referred to as $p\text{O}_2(\text{A})$ or $p_\text{A}\text{O}_2$, is the partial pressure of oxygen in alveolar gas. It is a primary component in the detection of gas exchange indices. The following equation[16,28] is used to estimate $p\text{O}_2(\text{A})$.

$$p\text{O}_2(\text{A}) = p_\text{I}\text{O}_2 - p_\text{A}\text{CO}_2 \times \left(F_\text{I}\text{O}_2 + \frac{1 - F_\text{I}\text{O}_2}{\text{R}}\right)$$

where

$$p_\text{I}\text{O}_2 = F_\text{I}\text{O}_2 \times (p\text{total} - p\text{H}_2\text{O})$$

R = gas exchange ratio

The 800 system does not report alveolar oxygen tension, but uses the $pO_2(A)$ value to calculate the alveolar-arterial oxygen tension difference and the arterial-alveolar oxygen tension ratio.

Alveolar-Arterial Oxygen Tension Difference

The alveolar-arterial oxygen tension difference, $pO_2(A–a)$, which is sometimes abbreviated as $A–aDO_2$, is useful as an index of gas exchange within the lungs if the ctO_2 measurements are not available. The following equation[16,28] is used:

$$pO_2(A–a)(T) = pO_2(A)(T) – pO_2(a)(T)$$

where $pO_2(A)(T)$ is the temperature corrected oxygen tension of alveolar gas and $pO_2(a)(T)$ is the temperature corrected oxygen tension of arterial blood.

Arterial-Alveolar Oxygen Tension Ratio

The arterial-alveolar oxygen tension ratio, $pO_2(a/A)$, which is also referred to as the a/A ratio, provides an index of oxygenation that remains relatively stable when F_IO_2 changes. It is useful in predicting oxygen tension in alveolar gas. The following equation[29] is used:

$$pO_2(a/A)(T) = \frac{pO_2\,(a)(T)}{pO_2(A)(T)}$$

where $pO_2(a)(T)$ is the temperature corrected oxygen tension of arterial blood and $pO_2(A)(T)$ is the temperature corrected oxygen tension of alveolar gas.

Respiratory Index

The respiratory index (RI) is the ratio of the alveolar-arterial blood oxygen pressure difference to arterial pO_2. RI, another a means of assessing the extent of pulmonary shunting, can be used instead of the alveolar-arterial oxygen tension difference [$pO_2(A–a)$]. Because RI is a ratio and not an absolute value, it does not present the inherent problems that are seen with the $pO_2(A–a)$ value. The following equation[16] is used:

$$RI(T) = pO_2(A–a)(T) / pO_2(a)(T)$$

where $pO_2(A–a)(T)$ is the temperature corrected alveolar-arterial oxygen tension difference and $pO_2(a)(T)$ is the temperature corrected oxygen tension of arterial blood.

Calcium Adjustment for pH

Ionized calcium values are dependent upon sample pH. The calcium value adjusted to pH of 7.40 reflects the true ionized calcium concentration of blood normalized to pH 7.40. Calcium is corrected according to the following equation.[30]

$$\text{adjusted } Ca^{++} = Ca^{++} \text{ measured} \times 10^{-0.178\ [\text{required pH} - \text{measured pH}]}$$

Calcium value is adjusted only when pH, at 37°, is between 7.2 and 7.7, since no reliable, published, clinical data is available outside that range.

Anion Gap

The anion gap (AnGap) is an approximation of the difference between unmeasured cations and unmeasured anions. Historically, several formulas have been used to mathematically approximate the balance of these unmeasured ions.

An anion gap result is of twofold value in a clinical laboratory. Primarily, abnormal anion gap results indicate electrolyte imbalance or other conditions where electroneutrality is disrupted, such as seen with diabetes, toxin ingestion, lactic acidosis, or dehydration. Secondly, the anion gap result is useful for quality assurance of laboratory results. If an increased or decreased anion gap result is calculated from a non-diseased individual this indicates the possibility to one or more erroneous electrolyte results.

The 800 system calculates the anion gap based on the following analytes:

$$\text{AnGap} = (Na^{+} + K^{+}) - (Cl^{-} + HCO_3^{-}\text{act})$$

The bicarbonate (HCO_3^{-}) in the above formula is also derived using the Henderson-Hasselbalch equation for determining bicarbonate calculations.

Arterial-Venous (a-v) Studies

When mixed venous blood gases from the pulmonary artery are combined with arterial blood gas measurements, the results frequently clarify the cardiopulmonary status and assist in determining appropriate therapeutic procedures to be initiated. This section describes the parameters associated with a-v studies.

Arterial Oxygen Content

The oxygen content of arterial blood ($ctO_2(a)$) is a determination of the total oxygen carried by the arterial blood, including the oxygen bound to hemoglobin and the oxygen dissolved in plasma and in the fluid within the red blood cells.

The system determines the oxygen content of arterial blood, based on NCCLS recommendations[45] as follows:

$$ctO_2(a) = (1.39 \times ctHb \times FO_2Hb) + (0.00314 \times pO_2)$$

where 1.39 is the system default value for the oxygen binding factor.

Venous Oxygen Content

The oxygen content of venous blood ($ctO_2(v)$) is a determination of the total oxygen carried by the venous blood, including the oxygen bound to hemoglobin and the oxygen dissolved in plasma and in the fluid within the red blood cells.

The system determines the oxygen content of venous blood, based on NCCLS recommendations[45] as follows:

$$ctO_2(v) = (1.39 \times ctHb \times FO_2Hb) + (0.00314 \times pO_2)$$

where 1.39 is the system default value for the oxygen binding factor.

Arterial-Venous Oxygen Content Difference

The arterial-venous oxygen content difference ($ctO_2(a\text{-}v)$) refers to the oxygen difference between arterial and venous blood. It is a determination of the amount of oxygen released to the tissues per volume of blood. [46]

When this result is obtained using a mixed venous sample, it is useful as an indicator of changes in cardiac output and helps to assess the cardiac and metabolic factors affecting arterial oxygenation. [47]

The system determines the arterial-venous oxygen content difference as follows:

$$ctO_2(a–v) = ctO_2(a) – ctO_2(v)$$

a-v Extraction Index

The a-v extraction index (ctO$_2$([a-v]/a)) aids in the interpretation of the arterial-venous oxygen content difference and can indicate inadequate oxygen content in arterial blood or inadequate cardiac output to meet oxygen demands of the tissues. [50] The value is most properly determined using arterial blood and mixed venous blood.

The system determines the a-v extraction index as follows:

$$ctO_2([a–v]/a) = \frac{cO_2(a–v)}{cO_2(a)}$$

Oxygen Consumption Rate

The oxygen consumption rate (VO_2), which is also referred to as "oxygen uptake", is a determination of the volume of oxygen consumed by the body per minute. [48]

The system determines the oxygen consumption rate as follows:

$$VO_2 = cO_2(a–v) \times Qt \times 10$$

Oxygen Delivery

Oxygen delivery (DO_2), which is also referred to as "oxygen transport", refers to the volume of oxygen per minute that is transported to the tissues. [49]

The system determines oxygen delivery as follows:

$$DO_2 = cO_2(a) \times Qt \times 10$$

Physiologic Shunt

The physiologic shunt [Qsp/Qt(T)] is that portion of the cardiac output entering the left side of the heart that does not perfectly respire with the alveoli. The shunt calculation represents the best available means of delineating the extent to which the pulmonary system contributes to hypoximia. [50]

The system determines the physiologic shunt using the following equation:[32]

$$Qst/Qt(T) = \frac{ctO_2(c)-ctO_2(a)}{ctO_2(c)-ctO_2(v)}$$

where $ctO_2(c) = [1.39 \times ctHb \times (1 - FCOHb - FMetHb)] + (0.00314 \times A)$;

$A = [(F_IO_2/100) \times (pAtm - pH2O)] - \{pCO_2 \times [1.25 - (0.25 \times F_IO_2/100)]\}$;

$ctO_2(v)$ is for a mixed venous sample;

1.39 is the system default value for the oxygen binding factor.

Estimated Shunt

Pulmonary artery blood gases are not always readily available, but there may still be a need to determine changes in the physiologic shunt. The best alternative method for reflecting changes in the physiologic shunt is the estimated shunt [Qsp/Qt(est,T)] value, which is applicable to most hypoxemic patients with cardiovascular stability. [51]

The system determines the estimated shunt using the following equation:

$$Qst/Qt(est,T) = \frac{ctO_2(c)-ctO_2(a)}{[ctO_2(a\text{-}v)\ entered]+ctO_2(c)-ctO_2(a)}$$

where $ctO_2(c) = [1.39 \times ctHb \times (1 - FCOHb - FMetHb)] + (0.00314 \times A)$;

$A = [(F_IO_2/100) \times (pAtm - pH2O)] - \{pCO_2 \times [1.25 - (0.25 \times F_IO_2/100)]\}$;

1.39 is the system default value for the oxygen binding factor;

$[ctO_2(a\text{-}v)$ entered] uses 3.5 mL/dL, which is the system default value for the arterial-venous oxygen content difference.

Reference Ranges

As with all diagnostic tests, each laboratory should establish its own reference ranges for the diagnostic evaluation of patient results. Bayer Diagnostics recommends that the reference ranges listed below be used to evaluate patient results.

Parameter	Reference Range
pH	7.350 – 7.450*
pCO_2	35.0 – 45.0 mmHg* 4.7 – 6.0 kPa
pO_2	75.0 – 100.0 mmHg† 10.0 – 13.3 kPa
Na^+	135.0 – 148.0 mmol/L*
K^+	3.50 – 5.30 mmol/L*
Ca^{++}	1.13 – 1.32 mmol/L‡
Cl^-	98 – 106 mmol/L*
Glucose	66.8 – 93.2 mg/dL§ 3.7 – 5.2 mmol/L
Lactate	0.5 – 2.0 mmol/L*

* Tietz NW ed. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders, 1987; 864-891.

† Weisberg HF. Acid-Base pathophysiology in the neonate and infant. Annals of Clinical and Laboratory Science 1982; 12(4)249.

‡ Lentner C ed. Geigy scientific tables. Vol 3, 8th ed. Basel: Ciba-Geigy Ltd., 1984; 82-83.

§ Sabata V, Stubbe P, Wolf H. Energy metabolism in the premature fetus. Biology Neonate. 1971; 19:299.

Appendix J: Maintenance Checklist Charts

Appendix J provides Maintenance Checklist charts for you to record maintenance activities performed on the 800 system.

Make photocopies of these charts as necessary and record your maintenance activities according to the maintenance protocol of your laboratory.

Bayer

RAPIDLAB 800 MAINTENANCE SCHEDULE

Month/Year _____

Daily Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean exterior surfaces																															
Check reagent levels																															
Check printer paper																															
Check waste bottle																															
Check sample path temperature																															
Check barometer																															

Twice Weekly Maintenance	Week 1		Week 2		Week 3		Week 4	
Analyze High G/L								

Weekly Maintenance	Week 1	Week 2	Week 3	Week 4
Deproteinize the sample path				
Condition the sensors				
Check gas tank pressures				
Check the solution levels in the sensors				

Bayer

RAPIDLAB 800 MAINTENANCE SCHEDULE

Month/Year _____

Monthly Maintenance	1	2	3	4	5	6	7	8	9	10	11	12
Exchange the cleaning solutions												
Replace 7.3 buffer installed for 30 days												
Replace Cal G/L reagent installed for 30 days												
Inspect the capillary seal												

Bimonthly Maintenance	1	2	3	4	5	6
Replace 6.8 buffer and Wash/Zero reagents installed for 60 days						
Replace sample tubing						

Quarterly Maintenance	1	2	3	4
Clean the sample chamber				
Clean the hemolyzer				

Bayer

RAPIDLAB 800 MAINTENANCE SCHEDULE

Month/Year _____

Semiannual Maintenance	1	2
Replace the air filter (base model)		
Replace the air filter (CO-ox module)		
Replace the measurement module tubing		
Replace the CO-ox sample tubing		

Yearly Maintenance	
Replace the pump tubing	
Replace the reagent manifold vent filter (base model)	

Bayer

RAPIDLAB 800 MAINTENANCE SCHEDULE

Month/Year _____

Non-scheduled Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Technical Bulletin

from Bayer Business Group Diagnostics.

Reagent Water Quality

Introduction

Water quality is an important consideration in the laboratory because it can significantly affect the outcome of laboratory procedures and the measurement of patient samples.

This bulletin provides an overview of reagent water quality guidelines as specified by the National Committee for Clinical Laboratory Standards (NCCLS).[1] Use these guidelines to evaluate the reagent water quality in your laboratory and to determine the best method for obtaining the water quality you need.

Good laboratory practices suggest that you establish a protocol that supports the manufacturer's requirements for the instrument to:

- ensure optimum performance of automated laboratory instruments
- eliminate water quality as a source of problems when troubleshooting
- help you to meet requirements for state and federal laboratory certification

What is Reagent Water?

Reagent water is laboratory water that meets specifications for clinical laboratory use.[2,3]

The NCCLS has defined three grades of reagent water:

- Type I, the highest grade
- Type II, the intermediate grade
- Type III, the lowest grade

Table 1 lists the NCCLS specifications for the three types of reagent water. Use this information to determine the water quality in your laboratory. Refer to the NCCLS guidelines for common laboratory uses of Type I, Type II, and Type III reagent water.

Table 1. Reagent Water Specifications

Specification	Type I	Type II	Type III
Maximum bacterial content colony forming units per mL (CFU/mL) *	10 (preferably bacteria free)	1000	not applicable
pH	not applicable	not applicable	5.0 – 8.0
Minimum resistivity (megohm/centimeter at 25°C) †	10 (inline measurement by sensor or resistor)	1.0	0.1
Maximum silicate (mg/L) ‡	0.05	0.1	1.0
Particulate matter (µm) §	smaller than 0.22 µm (water is passed through a 0.22 µm filter)	not applicable	not applicable
Organic compounds **	pretreat with activated carbon	not applicable	not applicable

* Bacterial content: The number of colony forming units in water. Bacterial content is a water contaminant you measure to determine water quality.

† Resistivity: The ability of water to resist electrical conduction due to the ion content. Resistivity is the standard test measurement for determining water quality. The higher the resistivity, the lower the ion content and the better the water quality.

‡ Silicates: Compounds you remove to produce Type I reagent water.

§ Particulate matter: Undissolved (insoluble) substances larger than 0.22 µm are removed by the filter.

** Organic compounds: Compounds you remove to produce Type I reagent water.

Purifying Water

As with all diagnostic testing procedures, good laboratory practices suggest that you establish a protocol that supports the manufacturer's requirements for selecting the appropriate type of reagent water. You can then produce reagent water in your laboratory by setting up and maintaining a water purification system which uses the purification methods described in Table 2.

Table 2 describes some of the typical laboratory water purification methods.

Table 2. Water Purification Methods

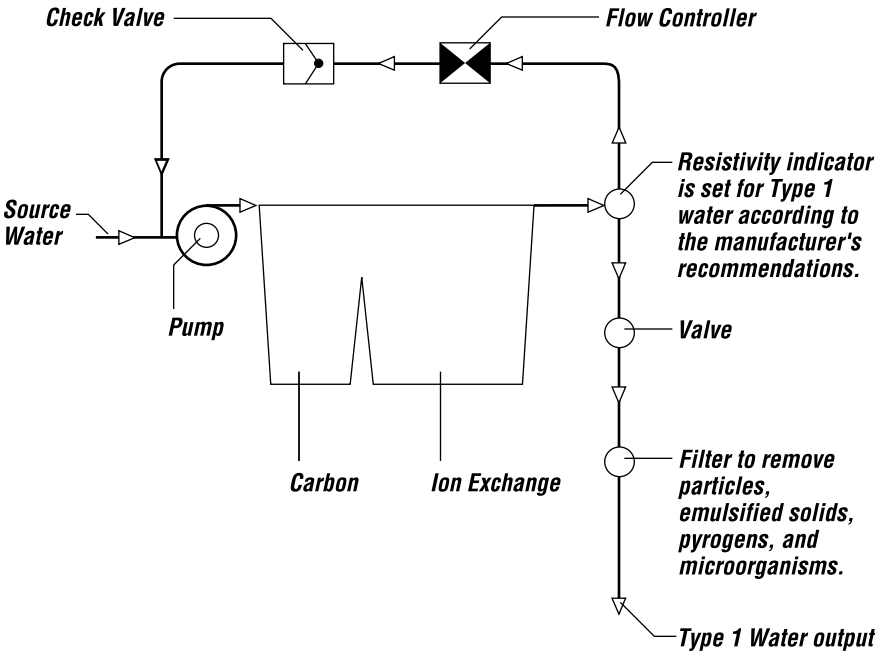
Method	Description
Distillation	Changes water from liquid to vapor and leaves behind impurities such as particulates and bacteria
Deionization	Uses synthetic resins to remove ionized impurities by ion exchange
Reverse Osmosis	Forces water under pressure through a semipermeable membrane to remove dissolved solids and organic impurities
Adsorption	Uses activated carbon, clays, silicates or metal oxides to remove organic impurities
Filtration	Forces water through a semipermeable membrane to remove insoluble matter, emulsified solids, pyrogens, and microorganisms

The quality of the reagent water you produce depends on the quality of the water you start with (source water), and the performance of your water purification system.

To produce the type of water you require, you may need a purification system that uses a combination of methods. For example, if you want to produce Type I water, you need a system that uses adsorption to remove organic impurities, ionization to remove ionized impurities, and filtration to remove particulates.

Figure 1 is an illustration of a water purification system that combines adsorption, deionization, and filtration to produce Type I water.

Figure 1. Water Purification System



Maintaining Water Quality

You can ensure that the reagent water supply in your laboratory consistently meets NCCLS guidelines by:

- storing reagent water properly
- testing for resistivity and contamination
- maintaining your water purification system

Establishing procedures for maintaining reagent water quality is also required for laboratory inspection and accreditation by the College of American Pathologists (CAP).[4]

Storing Reagent Water

Type I reagent water cannot be stored. Use it immediately after you produce it because it degrades quickly and no longer meets Type I reagent water specifications. Additionally, you cannot purchase Type I reagent water because its purity is not reliable.

Store Type II and Type III reagent water in glass or polyethylene bottles. Use it as soon as possible after preparation to reduce the risk of contamination by microorganisms.

Testing Reagent Water

To monitor water quality and detect problems with your water purification system, test reagent water regularly for resistivity and bacterial contamination. You may also want to send reagent water out of the laboratory periodically for independent evaluation. Record your test results and any corrective action.

Refer to the NCCLS specifications for information about recommended water testing methods.[1]

Maintaining your Purification System

Efficient operation and regularly scheduled maintenance of your water purification system is the key to optimizing the performance of the system and consistently obtaining reagent quality water. Preventative maintenance reduces the chance of the purification system introducing additional contaminants into source water and ensures that reagent water retains its purity when it is introduced into the laboratory instrument.

The following are suggested guidelines for maintaining water purification systems to ensure smooth operation and prevent system problems.

For Customized Water Systems . . .

- Change filters on carbon or membrane filter systems as required
- Use a recirculating pump to optimize performance and reduce contamination
- Filter the source water before treatment in reverse osmosis systems, and recirculate deionizers in closed loops to extend resin life

For Distillation Systems . . .

- Check the water vessels regularly for the presence of a slippery film
- Clean and disinfect the vessels as required with an agent that rinses well, such as H_2O_2
- Clean the boiler regularly to remove deposits
- Test routinely for contamination

For complete information about operation and maintenance requirements for your water purification system, refer to the manufacturer's specifications.

Problems Caused by Water

Using water that does not meet NCCLS guidelines can cause problems with clinical laboratory systems. Some common problems include:

- contamination of system components
- inaccurate patient and calibration results
- out-of range quality control results
- deterioration of lyophilized quality control material
- color changes and poor stability and performance of reagents

These problems can be caused by failure to use the appropriate type of reagent water, bacterial contamination, and inadequate maintenance of the water purification system.

Refer to the troubleshooting section in your system manual for more detailed information about problems caused by water that does not meet reagent water specifications.

References

1. National Committee for Clinical Laboratory Standards. Preparation and testing of reagent water in the clinical laboratory. 2nd ed. Villanova (PA): NCCLS; 1991 Aug. 37 p. (NCCLS Document C3-A2).
2. Tietz, Norbert W. Fundamentals of clinical chemistry, 3rd ed. Philadelphia: W.B. Saunders Company; 1987. 1010 p.
3. Kaplan, Lawrence A. Pesce, Amadeo J. Clinical Chemistry; theory, analysis, and correlation, 2nd edition. St. Louis: C.V. Mosby Company; 1989. 1212 p.
4. College of American Pathologists, Laboratory General Inspection Checklist Section 1, Quality of water, p. 8. Northfield, IL.1989.

Manufactured by:
Bayer Corporation
East Walpole, MA 02032-1597 USA

Bayer Argentina S.A.
Division Diagnósticos
Buenos Aires, Argentina

Bayer Australia Limited
Diagnostics Business Group
Scoresby, Victoria 3179, Australia

Bayer Austria GesmbH
GB Diagnostika
A-1164 Wien, Austria

Bayer Diagnostics
1050 Bruxelles, Belgium

Bayer S.A. Diagnostics
São Paulo SP, Brazil

Bayer Inc.
Toronto, Ontario
Canada M9W1G6 ETOBI

Bayer S.A.
Bogotá, D.C. – 6, Columbia

Bayer A/S
DK-2800 Lyngby, Denmark

Bayer OY
FIN 02270 Espoo, Finland

Bayer Diagnostics
92807 Puteaux Cedex, France

Bayer Vital GmbH & Co. KG
Geschäftsbereich Diagnostika
D-35463 Fernwald, Germany

Bayer Hellas AG
BG Diagnostics
151 25 Athens, Greece

Bayer Diagnostics Limited
Hong Kong

Bayer Diagnostics India Limited
Gujarat, India

Bayer S.P.A.
Divisione Diagnostici
20151 Milan, Italy

製造元：Bayer Corporation
輸入元：バイエル メディカル
株式会社
：Bayer Medical Ltd.
東京都渋谷区恵比寿 1-19-15
Tokyo 150-0013, Japan

Bayer Diagnostics Korea Ltd.
Seoul, Korea

Bayer de México, S.A. de C.V.
Division Diagnósticos
Delegagción Benito Juárez
México, D.F.C.P. 03100

Bayer B.V.
Division Diagnostics
3641 RT Mijdrecht
The Netherlands

Bayer As
N-1483 Skytta, Norway

Bayer Sp. z o.o.
02-326 Warsaw, Poland

Bayer Diagnostics Lda.
2795 Carnaxide, Portugal

Bayer Puerto Rico Inc.
Diagnostics Division
Carolina, Puerto Rico

Bayer (Pty) Ltd.
Isando
South Africa

Química Farmacéutica Bayer, S.A.
08029 Barcelona, Spain

Bayer AB
S-402 24 Göteborg, Sweden

Bayer (Schweiz) AG
Geschäftsbereich Diagnostika
8045 Zuerich, Switzerland

Bayer Taiwan Co., Ltd.
Diagnostics Division
Taipei, Taiwan, R.O.C.

Bayer Plc
Diagnostics Division
Newbury, RG14 1JA
United Kingdom

Bayer Corporation
Diagnostics Division
Tarrytown, NY 10591-5097 USA

107060 Rev. C 10/99

Bayer

Glossary

Accept	The F-key that lets you store QC results in a QC file and update the statistics in the QC file.
accession number	A number, not assigned by the 800 system, used to identify a sample. The number is usually assigned by the hospital or laboratory to cross reference the analysis for billing purposes.
action range	A range of values with upper and lower limits that the 800 system uses to evaluate patient sample results. Any sample results that are beyond these limits are flagged on reports and require immediate action by the operator.
air filter	The component that protects internal parts of the system from excessive dirt build-up. Inspecting the air filter is a regular maintenance task.
Analyte Performance Verification	A process developed by Bayer Diagnostics that lets you verify performance specifications for new test systems or methods before you report patient results.
Analyze	The key that begins sample analysis.
Analyze mode	The normal operating state in which you can analyze patient and QC samples and perform calibrations.
arrow keys	Left, right, up, and down keys that allow you move the cursor through menus, from field to field, and through an option list to select an option.
atmospheric pressure	Barometric pressure.
Auto Accept QC	The QC setup option that lets you automatically accept QC results into a QC file and updates the statistics in the file.
Auto Clean	An automatic system function that initiates a cleaning cycle once every 24 hours to clean the system with a cleaning solution.
Auto ID	The QC setup option that automatically identifies a QC sample and assigns it to a QC file at the endof analysis.
Auto Move	The system setup option that automatically moves a capillary sample into position for analysis.
Auto Repeat	The calibration setup option that automatically repeats a calibration up to two times when drift limits are exceeded.

Auto Send	The system setup option that automatically sends patient or QC sample results to a laboratory information system (LIS) or data management system.
Backup	The Disk Utilities menu option that copies all the system files to diskettes for storage. Use backup to prevent loss of data in case of a hard disk failure.
Bar Code Scanner	The Troubleshooting menu option that lets you perform a bar code scanner test, which tests the ability of the bar code scanner to read a test pattern.
bar code scanner	An optical device that enters patient ID and accession numbers, quality control, and reagent information into the system by scanning bar code labels.
Barometer	The Calibration menu option that lets you enter the true atmospheric (barometric) pressure to calibrate the internal atmospheric pressure sensor.
base model	The part of the 800 series system that includes the measurement module, fluidic components, and reagents. For example, the base model for an 865 is an 860.
biosensor	A device that utilizes an active biomolecule, such as an enzyme, to measure analyte levels in a sample. The glucose and lactate sensors are biosensors.
calibration	The process of testing and adjusting the electronic signal from a sensor. The 800 systems automatically perform one-point calibrations and two-point calibrations at regular intervals for each measured parameter.
calibration drift	The degree of deviation from the last calibration for the selected parameter.
Calibration Setup	The Operating Setup menu option that lets you define drift limits, enter calibration gas values, and set calibration frequency and auto repeat options.
Cancel	The F-key that discontinues an activity. For example, if you press Cancel during a calibration, the system stops calibrating, initiates a wash, and displays the Ready screen.
Change Sample Type	The F-key that lets you select a sample type for the next sample you analyze.

check box	A box next to each option in a list of options that indicates whether the option is chosen. If the option is chosen, the box is filled in. If the option is not chosen, the box appears empty. You can select more than one option from a list of options with check boxes.
Clear Entry	The F-key that deletes a character or the entire entry from a field. Pressing the Clear Entry key once deletes a single character. Pressing the Clear Entry key twice in quick succession deletes the entire entry. The cursor returns to the beginning of the field to allow you to enter new data.
Communications	The System Setup menu option that lets you define parameters for connecting external devices to the 800 system. Also a Troubleshooting menu option that lets you to perform the External Loopback test.
Condition	The Maintenance menu option that performs the conditioning maintenance procedure, which cleans deposits off of the glass pH and Na^+ sensors.
conditioner	A solution used during the conditioning procedure that cleans and conditions the sensors.
CO-oximeter (CO-ox)	A device that spectrophotometrically measures the absorption of whole blood at several wavelengths to determine the concentration of hemoglobin and its derivatives in whole blood.
CO-ox zero	A sequence, during a one- or two-point calibration, that calibrates the CO-ox optical system by establishing the value of a colorless fluid (7.3/CO-ox Zero reagent). No value is reported on the screen.
Correlation	The Operating Setup menu option that lets you specify correlation coefficients (slope and offset values) so that the results from the system match the results of a reference analyzer in your laboratory.
cursor	A visual device that indicates the active area of the screen. For example, when the cursor moves to a field, the field is enclosed by a box, or if a box already exists, the border becomes darker. You move the cursor by pressing an arrow key or the Enter key.
CVM	Calibration Verification Material. A material formulated to verify the calibration of blood gas, electrolyte, and total hemoglobin systems throughout the reportable range.

Data Recall	The menu option that lets you access stored data, such as patient, quality control, and calibration data, and workload statistics.
D code	A diagnostic code, which appears in the status area of the screen, that you use as a reference when troubleshooting. An example of a D code is D3 Slope Error.
default values	Values assigned by Bayer Diagnostics during manufacturing. You can change default values through setup menus.
Deproteinize	The Maintenance menu option that lets you clean the sample path to remove protein deposits.
deproteinizer	A cleaning solution that removes protein deposits from the sample path.
Discard	The F-key that lets you store QC data in a discard data file and does not update the statistics.
discard data file	A temporary storage file for discarded QC results. The system does not place discarded QC data into an active file or update the statistics. You can retrieve the discarded data using the Data Recall function if the data was accidentally discarded. Also called File 14.
diskette	A 3.5-inch (90 mm) disk to which you can copy data files from the hard disk.
diskette drive	The opening located behind the screen into which you insert diskettes.
Disk Utilities	The System Utilities menu option that lets you perform disk utilities functions, including Backup, Archive, View Archive, Restore, and Install.
Done	The F-key you press when you have finished selecting options and have entered data in a form. When you press Done, the system accepts the changes.
drift limits	The values used to determine excessive drift during a calibration. You enter acceptable drift limits for each parameter through the Calibration Setup menu.
endpoint	The final measurement value obtained from a sensor.
Enter	The key you press when you have finished typing information into a field or a when you have made a selection from a list or menu.

External Loopback	The Communications menu option that performs an external communications loopback test. This test verifies the internal communications through the serial ports and external cables.
File 13	A storage file containing QC data that Bayer Diagnostics field service engineers use during troubleshooting. You can delete the contents of the file, but you cannot access the file data.
File 14	A temporary storage file for discarded QC results. The system does not place data into an active QC file or update the statistics. You can recall the data in this file using the Data Recall function if it was accidentally discarded.
fixed time calibrations	A method of determining intervals between calibrations in which you determine the maximum time between one-point and two-point calibrations. You determine fixed time calibration through the Calibration Setup menu.
F-keys	The five function keys (F1 through F5) located below the screen that are associated with the labels displayed on the bottom line of the screen. The key functions can change as you move from screen to screen.
flag	A symbol that appears on some screens and printed reports that indicates that the system detects an unexpected result or measurement. For example, the single up arrow (↑) on a patient report indicates that the sample result is above the reference range or that the calibration result is above the high drift limit.
flexible time calibrations	A method of determining calibration intervals. The system uses an algorithm to determine the time between calibrations based on sensor status and previous calibration results (calibration drift).
Fluid Detector	The Fluidics System menu option that lets you test fluid detectors 1, 1A, and 2 with air, clear liquid, or opaque liquid (blood) and test fluid detectors 3 and 4 with air or clear liquid.
fluid detector	A sensor that detects fluid in the sample path. There are five fluid detectors: 1, 1A, 2, 3, and 4.
Fluidics System	The Troubleshooting menu option that lets you test the fluidic system.

fluidic system	The subsystem responsible for the movement of fluids in the 800 system, including tubing, pumps, fluid detectors, waste system, solenoid valves, and reagents.
frame	The boxed area on a screen that displays information and messages, such as message boxes, fields, and option lists.
Global QC Settings	The QC Setup menu option that turns Auto ID (automatic identification) and Auto Accept QC on or off.
hard disk	A device that stores the system programs and data files required for system operation.
Help	The key that lets you view additional information about the current Analyze mode screen or an index of topics about the Menu mode. You can also use Help during troubleshooting.
hemolyzer	A chamber in the CO-ox sample path that uses ultrasonic sound vibrations to rupture red blood cells.
highlight bar	The area of the screen that appears in reverse video to indicate the selected choice in a scroll list or menu.
HIS	Hospital information system. A computer system that is used for data management throughout the hospital.
Home	The key that returns the system to the Ready screen when the system is ready for analysis.
initialize	The function performed during system installation or startup that prepares data files for accepting the data you enter in the 800 system.
Install	The Disk Utilities menu option that transfers system software and upgrades from the installation disk to the hard disk.
instruction line	An area on the screen that contains one line of directions for moving through or working with the current screen.
keyboard	A device that provides a set of alphanumeric and other keys that you use to enter information into the system.
keypad	The area of the system that contains the F-keys, arrow keys, numeric keys, and other keys through which you interact with the system.

Levey-Jennings chart	A visual representation of measured QC values used to detect results that fall outside of the established control limits and to observe trends or shifts in control values.
LIS	Laboratory information system. A computer system that is used for data management in one or more laboratories.
Maintenance	The Menu screen option that accesses maintenance functions, such as Deproteinize, Condition, and Prime.
Measurement	The Troubleshooting menu option that tests electrical sensor output.
Measurement module	The area of the system that measures the analytes in a sample. It consists of the sensors, preheater, measurement block, and sample ground/temperature sensor.
Menu mode	The system operating state that lets you perform all system functions other than sample analysis. Menu mode accesses the Calibration, Troubleshooting, Maintenance, Data Recall, Operating Setup, System Setup, System Utilities, and Service Setup menus.
Menu screen	The screen that appears when you are in Menu mode. From this screen, you can access all system functions other than sample analysis.
message box	A box that displays information that requires you to perform an action or select an option by pressing an F-key. The message box remains on the screen until you respond.
Microsample	A sample that has a total volume less than required for a standard capillary/syringe analysis. When measuring a microsample, the system measures pO_2 and pCO_2 and then advances the sample to measure the remaining parameters.
numeric keys	The keys on the keypad that you use to type numbers.
offset	The value obtained through linear regression analysis that represents the variance that is constant between the data points in one set of data and any of the data points in another set of data. An offset of 0.0 indicates no variation.

Operating Setup	The Menu screen option that lets you define QC setup, reference and action ranges, patient data entry, report formats, measurement units, parameter names, printing options, calibration setup, printing options, and correlation coefficients.
option button	A diamond symbol that appears next to an option in an option list. When an option button is filled in, that option is selected. You can select only one option in an option list.
option list	A list of two or more options in a frame that you select by highlighting the required option. An option list can contain check boxes, option buttons, or a scroll list.
panel	A set of parameters, such as pO_2, pCO_2, and pH, that are measured by an 800 system. You can select a panel for the system through the System Setup menu. The default panel is All Parameters.
Paper Advance	The key that advances the paper in the roll printer.
Paper Spool	The key that tightens the printer paper on the spool.
Parameter Names	The Operating Setup menu option that lets you select the chemical symbols to identify parameters.
Parameters	The System Setup menu option that lets you turn on and off individual parameters for sample analysis.
password	A set of characters (up to eight) that lets you access certain system functions. An 800 system has two passwords: a system password that lets you operate the system and a menu password that lets you use designated menus. You can define separate passwords for accessing the system and for accessing menu options. You define passwords through the System Setup menu.
patient sample	Blood or a volume of expired gas collected from a patient. The system uses the sample to analyze specific parameters and displays the results.
*p*ATM	Atmospheric (barometric) pressure.
PC board	Printed circuit board. A component that performs specific electronic functions within the system.
pH only	The Sample Type menu option that lets you analyze samples that require only a pH measurement. This feature is available only on 840 systems.

platen	The component in a pump that, in conjunction with the roller cage, applies pressure to the tubing to move liquids through the system with a pumping action. The pumping action seals the tubing to prevent a vacuum from reaching the measurement module.
power supply	The component that accepts the voltage from the power input, converts it from AC to DC, and directs it through the system.
Prime	The Maintenance menu option that pumps reagents through the system to remove bubbles from the reagent tubing.
Print	The F-key that lets you print a report.
printer	The component of the system that generates printed reports. The 800 system has a built-in roll printer. You can also connect the ticket printer or a parallel printer to the 800 system.
Printing Options	The Operating Setup menu option that lets you select a report type, turn on automatic printing, enter the number of copies to be printed, and select a printer.
Purge	A function that moves solutions through the measurement module, thereby automatically maintaining the characteristics of the sensors when there has been no wash, sample, or calibration operation for a period of time.
QC	Quality control.
QC sample	A unit of material that lets you perform quality control analysis.
QC Setup	The Operating Setup menu option that lets you create or edit QC files.
quality control	Quality control (QC) analysis is an 800 system function that lets you evaluate the performance of the system and make sure that results of patient sample analysis are accurate and reliable.
Ready screen	The system default screen. You use the Ready screen to analyze all types of samples. You can access the Ready screen (if the system is ready for analysis) from other screens by pressing the Home key.

reagent	A substance that the system uses because of its chemical or biological activity to detect or measure the analytes present in a patient sample, to analyze a QC sample, to calibrate the system, or to wash system tubing.
reagent fitting	The component of the reagent manifold that attaches to the reagent bottles and lets the reagents enter the system.
reagent manifold	The component of the system that contains solenoid valves and tubing that direct the movement of reagents and gases through the system.
reagent water	Water purified for clinical laboratory use as described by the National Committee for Clinical Laboratory Standards.
Recall Data	The Menu screen option that lets you access data stored in the system. You can use this menu option to view, edit, and print reports of stored data.
reference limit	The value that determines whether a patient sample or calibration result is outside the expected range.
reference range	A range of values with upper and lower limits that the system uses to evaluate patient sample results. The reference range represents the range within which results are expected to fall.
reference sensor	The sensor that works with the pH, Na^+, Cl^-, and Ca^{++} sensors to create an electrochemical cell. The system compares the fixed potential of the reference sensor to potential generated by the sample at the membrane of a measuring sensor to measure an analyte in the sample.
Reject	The F-key that lets you store QC results in a QC file, but not update the statistics in the QC file.
Report Formats	The Operating Setup menu option that lets you define screen reports and select a format for printer reports.
Reporting Resolution	A system option that determines whether results for certain parameters appear in high resolution (more significant digits) or low resolution (fewer significant digits). For example, the high resolution option for pH is 0.001 and the low resolution option is 0.01.

required fields	Patient data entry fields in which you must enter a value. For example, if the Patient Temp field is a required field, you must enter a patient temperature in the field before you can access the next screen. You define required fields in Setup.
Restore	The Disk Utilities menu option that copies backed up patient, quality control, CVM, calibration, maintenance, diagnostic, and setup files from diskettes to the hard disk. Restoring data replaces the corresponding data on the hard disk.
roller cage	The component of a pump that rotates and, in conjunction with the platen, causes liquids to move through the system via a pumping action.
Roll Printer	The Troubleshooting menu option that performs a roll printer test. This test generates all characters that the system prints in all positions on the roll printer.
RS-232	A communication standard that defines hardware requirements used for serial ports to connect printers and other devices to the system.
sample connector	The component that splits the sample path to allow a sample to go to both the measurement module and the CO-ox module.
sample door	The component that that lets you introduce a patient or QC sample into the system. It also determines the sample type and the volume.
Sample Entry	The Fluidics System menu option that lets you perform sample door tests.
sample ground/ temperature sensor	The sensor that detects the sample temperature and provides a sample ground for stable sensor readings.
sample port	The area where samples are introduced into the system. The sample port is designed to accept a variety of sample collection devices.
sample source	The origin of a patient sample: arterial, venous, mixed venous, or expired gas.
Sample Type	The option list on the Ready screen that lets you select the sample type: syringe/capillary (default sample type), quality control (QC), pH only, or microsample.
scroll list	A list of options in a frame. You use arrow keys to move through the list and select an option.

Security Options	The System Setup Menu option that lets you define passwords for the system and for Menu mode.
sensor	A device designed to detect a particular analyte in a sample. The pH and the pCO_2 sensors are examples.
sensor status indicator	The area on the screen that indicates the current status of each sensor in the system.
septum	The membrane on the reagent bottle through which the fitting on the reagent manifold passes.
sequence number	A unique number assigned by the system to every sample analysis, QC analysis, and calibration.
Shutdown	The System Utilities menu option that lets you shut down the system before performing service.
slope	The value obtained through linear regression analysis that represents the relationship between two sets of data. A slope of 1.0 indicates identical data sets.
slope drift	The difference between the results for the current slope and the theoretical value for a calibration.
solenoid valve	The component associated with opening and closing the path within the fluidic system to control the passage of fluids and gases.
Standby	The System Utilities menu option that lets you place the system into an inactive mode when you are not analyzing samples. The system does not perform automatic calibrations while in standby.
status area	The top portion of the screen that displays the status name, system messages, sensor status indicators, and date and time.
Status Event Log	The Data Recall menu option that lets you view diagnostic codes and system messages and print the Status Event Log report. Also a report that lists the last 72 hours of status messages, D codes, and samples for which required data entry is incomplete.
Stop System	The Maintenance menu option that lets you disable sample analysis and automatic calibration functions so that you can perform maintenance activities.
System ID	The Service Setup menu option that lets a Service Representative identify the system model and enter the system ID and installation date.

system message	A message that appears in the status area of the screen that describes the status of certain system operations.
System Options	The System Setup menu option that lets you define system options. The options include Reporting Resolution, Beeper Volume, Auto Move Capillary Sample, and Roll Printer.
System Setup	The Menu screen option that lets you define system functions. You can define the date and time, enable and disable parameters, define panels, define communication parameters, and define system options.
System Utilities	The Menu screen option that lets you access file and system management functions, including Standby, Disk Utilities, and Shutdown.
Target limit	The values that determine the limits above and below the target mean for QC sample analysis.
Temp/*p*Atm	The Troubleshooting menu option that lets you perform a temperature test and a barometer test.
Troubleshooting	The Menu screen option that lets you access diagnostic tests.
Units/Values	The Operating Setup menu option that lets you select measurement units that the system uses to display primary, entered, and calculated parameters.
user interface	The components of the 800 system, including the screen, keypad, and printer that let you direct system activities.
Valves	The Fluidics System menu option that lets you perform automatic and manual valve tests.
View Status	The F-key that displays a status log that lists the last 72 hours of diagnostic messages and samples for which required data entry is incomplete. The View Status F-key only appears if the status log contains messages.
Wash	A Maintenance menu option that lets you perform a wash.
waste cap	The component that seals the waste bottle.
waste components	The components that collect the waste reagents and samples from the system and then clean and prepare the system for the next activity. They consist of a waste bottle, waste detector probes, a waste cap, a pump, and tubing.

waste detector	The component beneath the waste bottle that detects the presence of the waste bottle and detects the amount of liquid in the bottle to prevent waste overflow.
work area	The area on the screen that displays the screen elements that pertain to the function you are performing. The contents of the work area varies with the function. For example, during sample analysis, the system displays a data entry form you use to enter patient demographic data, and when analysis is finished, it displays results.
Workload Stats	The Data Recall menu option that lets you display month-to-date and year-to-date workload statistics, including the current number of patient samples, quality control samples, and calibrations stored by the system. It also displays the total cycle count, which is the total number of wash and purge sequences the system has performed since installation.

Index

Symbols

Numbers

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W